ASBESTOS WORKSHOP:
SAMPLING, ANALYSIS, AND RISK ASSESSMENT

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Report Documentation Page

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Presentation Objective

Provide an overview of asbestos-related risk assessment:

- Focus on risk from asbestos contamination in soil
- Review *state of the practice* and a look at what might be coming in the future

Presentation Outline

1. Asbestos Overview
2. Asbestos Definitions and Uses
3. Regulatory Environment
4. Sample Collection and Analysis
5. Fiber Counting and Statistical Methods
6. Asbestos Risk Assessment: Principles and Methods
7. Asbestos Risk Assessment: Example

Clearly multi-disciplinary – asbestos chemists, field teams, regulatory expertise, statistics, toxicology, risk assessment

Asbestos Overview

Asbestos: Definition and Uses

- A naturally-occurring pliant and fibrous mineral with heat-resistant properties
- Serpentine Class: joint compound, 'popcorn' ceilings, brake pads, tiles and shingles, fabric, insulation, etc.
  - chrysotile
- Amphibole Class: insulating board and tiles, asbestos-cement sheets and pipes, other insulation
  - various types (crocidolite, amosite, etc)

Asbestos: Problem Summary

Asbestos fibers are inhaled and remain in the lungs and in the pleural cavity holding the lungs

Pulmonary macrophage (a specialized type of white blood cell) attempting (and failing) to engulf and digest crocidolite asbestos fibers.

Asbestos: Non-Cancer Diseases

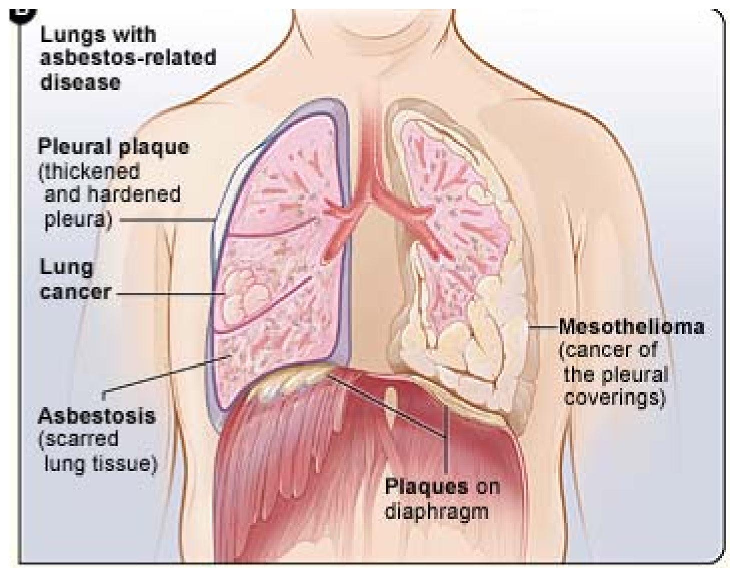
Asbestosis (fibrosis of the air sacs of the lungs) and pleural fibrosis (fibrosis of the lining of the cavity holding the lungs)

Chest x-ray showing areas of scarring related to asbestosis.

Asbestos: Cancers

Lung cancer and mesothelioma (a cancer of the lining of the pleural cavity holding the lungs) are the primary cancers

Asbestos-related diseases, including lung cancer and mesothelioma.



Adapted from a National Institutes of Health image

Asbestos Environmental Sampling

Stationary air sampling

Personal air sampling

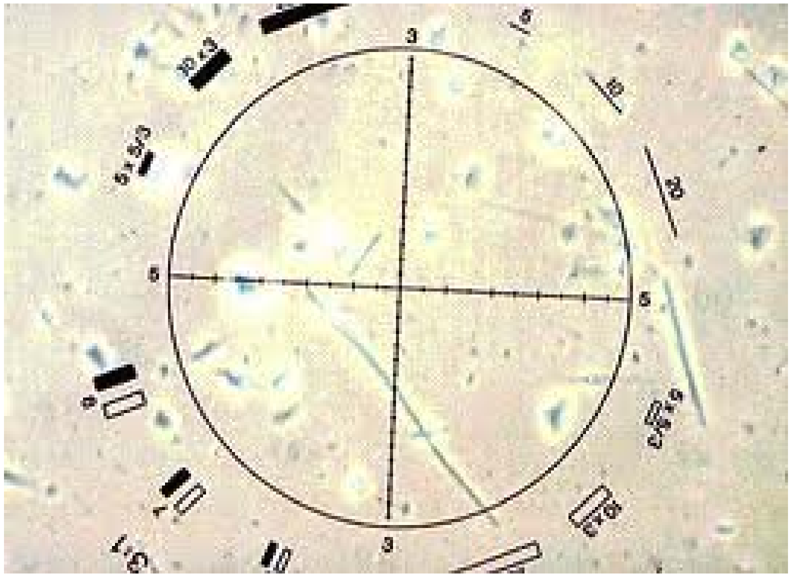
Soil sampling

Asbestos Laboratory Analysis

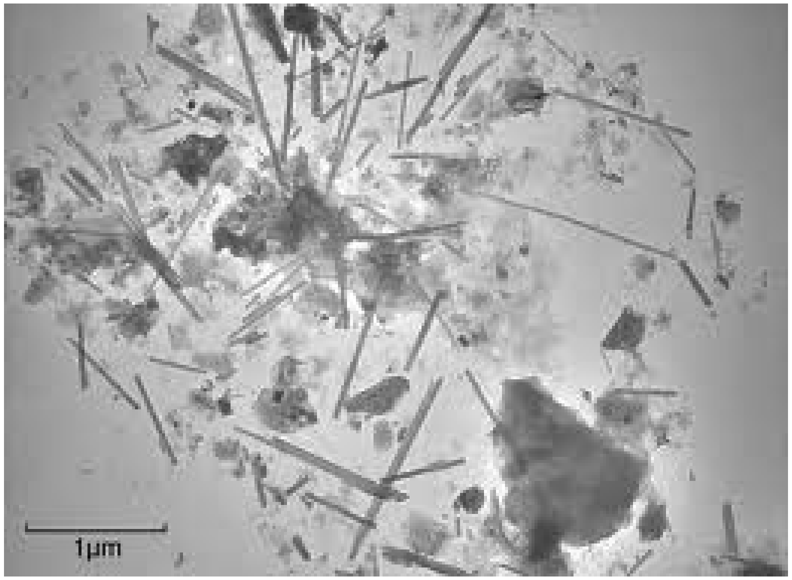
Phase Contrast Microscopy (PCM)

Transmission Electron Microscopy (TEM) – asbestos fibers can be distinguished by type and thin fibers can be observed

PCM analysis



TEM analysis; Chrysotile



Asbestos Fibers of Concern

- Different protocols exist for defining and counting fibers. Some examples include:
  - >5 µm in length, >0.4 µm in width, with an aspect ratio of ≥3:1
    - EPA's 1986 inhalation unit risk cancer toxicity value based on PCM analysis
  - >10 µm in length and <0.4 µm in width
    - Berman and Crump, 2003; based on TEM analysis and more recent epidemiology studies

Defining Exposure Concentration

- Counting issues
  - Fibers, bundles, clusters, matrices
  - Dimensions of risk interest
- Statistical approaches
  - Data Quality Objectives
  - Poisson counting statistics
  - Poisson clustering, mixture models
- Direct air measurements or modeling?
- Means or upper confidence limits?
- Detection Limits?

Asbestos Toxicology

- EPA's 1986 Inhalation Unit Risk (IUR) and 2008 Asbestos Superfund Framework: All structures counted according to the protocol are assigned the same IUR
  - But now using TEM/PCMe instead of PCM
- Berman and Crump, 2003 and later: Separate IUR values for amphiboles and chrysotile; separate IUR values based on smoking status and gender

Asbestos Risk Calculation

$$\text{Risk} = \boxed{\text{Exposure}} \times \boxed{\text{Toxicity}}$$

$$= \boxed{[\text{Air}] \times \text{ET} \times \text{EF}} \times \boxed{\text{IUR}}$$

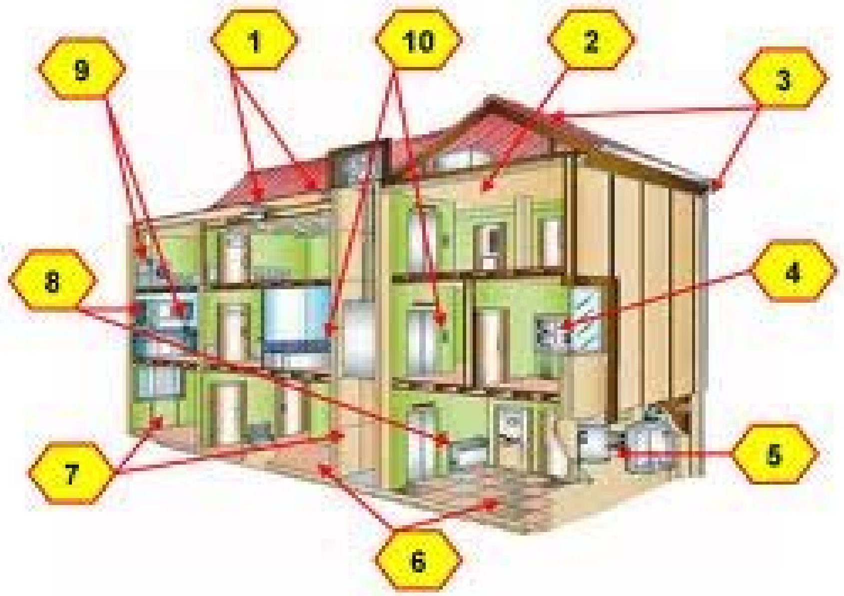
$$= \text{f/cm}^3 \times {}^{hour/day}/_{24} \times {}^{day/yr}/_{365} \times \text{risk per (f/cm}^3)$$

The duration (yr) of exposure is incorporated into the inhalation unit risk (IUR) toxicity value.

Asbestos Evolving State of Practice

- Definition of asbestos – still evolving
- Use – curtailed in the US
  - Remaining contamination issues
- Regulations – guidance still evolving
- Sampling and analysis
  - Methods evolving
- Counting and statistics
  - Counting issues remain (what to count)
  - A wider array of statistical methods is needed
- Toxicology and risk assessment
  - Differences of opinion on risk factors

Asbestos: Definitions and Uses



What is Asbestos?

- “any of several minerals (as chrysotile) that readily separate into long flexible fibers, that cause asbestosis and have been implicated as causes of certain cancers, and that have been used especially formerly as fireproof insulating materials” – Merriam-Webster

Chrysotile

What is Asbestos?

- "a heat-resistant fibrous silicate mineral that can be woven into fabrics, and is used in fire-resistant and insulating materials such as brake linings. The asbestos minerals include chrysotile (white asbestos) and several kinds of amphibole, notably amosite (brown asbestos) and crocidolite (blue asbestos)." – Oxford Dictionaries

Crocidolite

Classes of Definitions

- Commercial
  - Materials used for industrial activities
- Regulatory
  - Materials regulated by agencies and organizations
- Geological
  - Mineralogical
  - Morphological

Asbestos: Commercial Definition

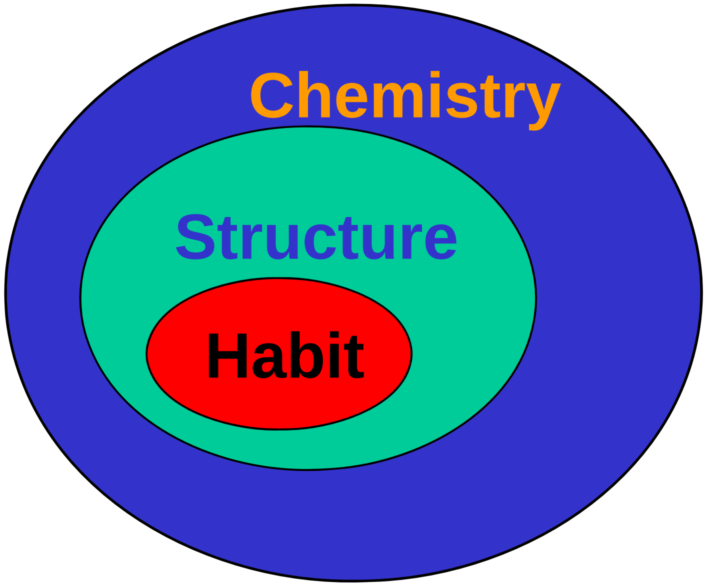
- Naturally occurring mineral fibers
- Selected for useful properties
  - Long flexible mineral fibers
  - High tensile strength
  - Durability
  - Heat resistance
  - Acid/alkaline resistance (amphiboles)
- The general term "asbestos" was applied to mineral fibers selected for these uses

Asbestos: Regulatory Definition

- Occupational Safety and Health Administration (29 CFR 1910.1001)
  - “"Asbestos" includes chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos, actinolite asbestos, and any of these minerals that have been chemically treated and/or altered.”
- U.S. Environmental Protection Agency
  - Toxic Substances Control Act, Asbestos Hazard Emergency Response Act
  - Clean Air Act, National Emission Standards for Asbestos

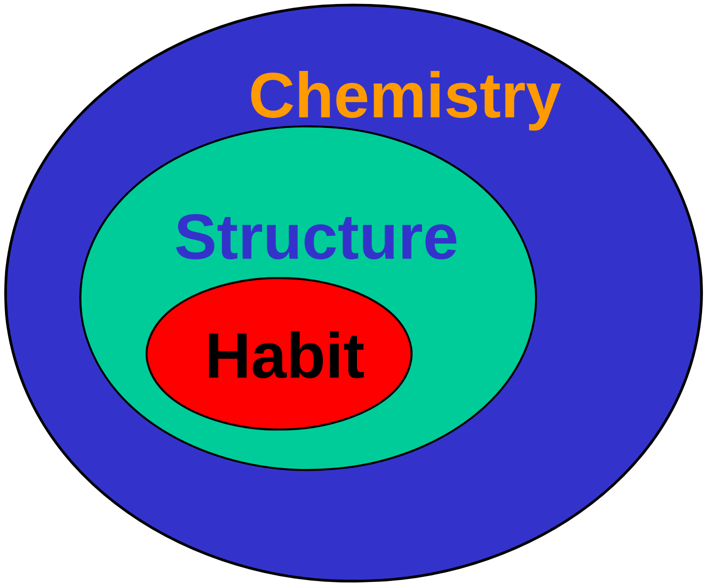
Asbestos: Geological Definition

- Silicate Minerals – basic chemistry
  - Silicon and oxygen
    - Tetrahedron shaped ionic group (SiO_4) can form different polymeric structures
  - Cations present
    - (Ca, Fe^{+2}, Al, Mg, etc.)
- Group/Class
  - Serpentine
    - Chrysotile
  - Amphibole
    - Crocidolite, amosite, anthophyllite, tremolite, actinolite

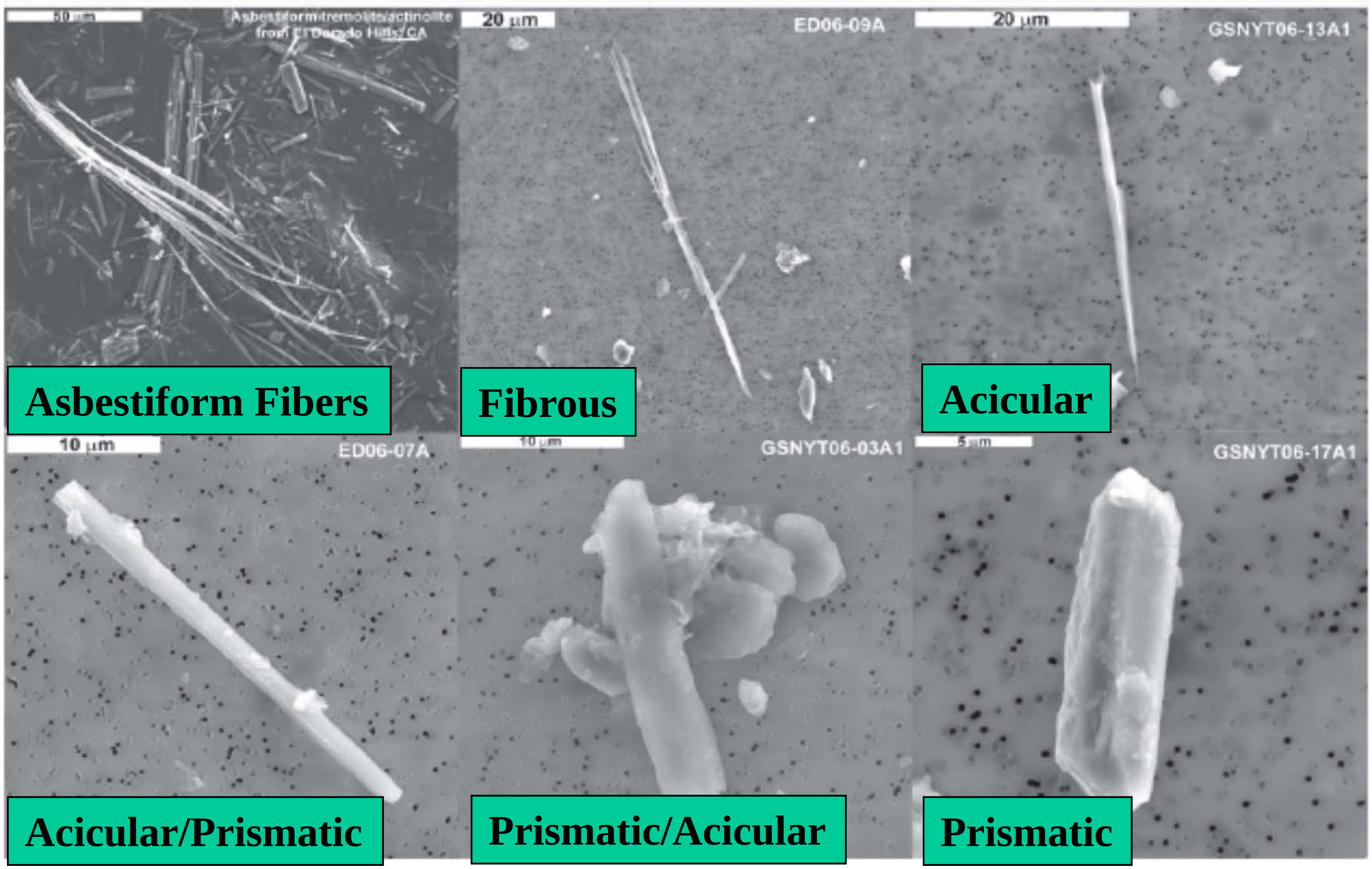


Asbestos: Geological Definition cont…

- Further classification
  - Structure
    - Fibrous
    - Acicular
    - Prismatic
  - Habit of formation
    - Asbestiform
    - Non-asbestiform (e.g., massive)



Morphology - Structures



Habits

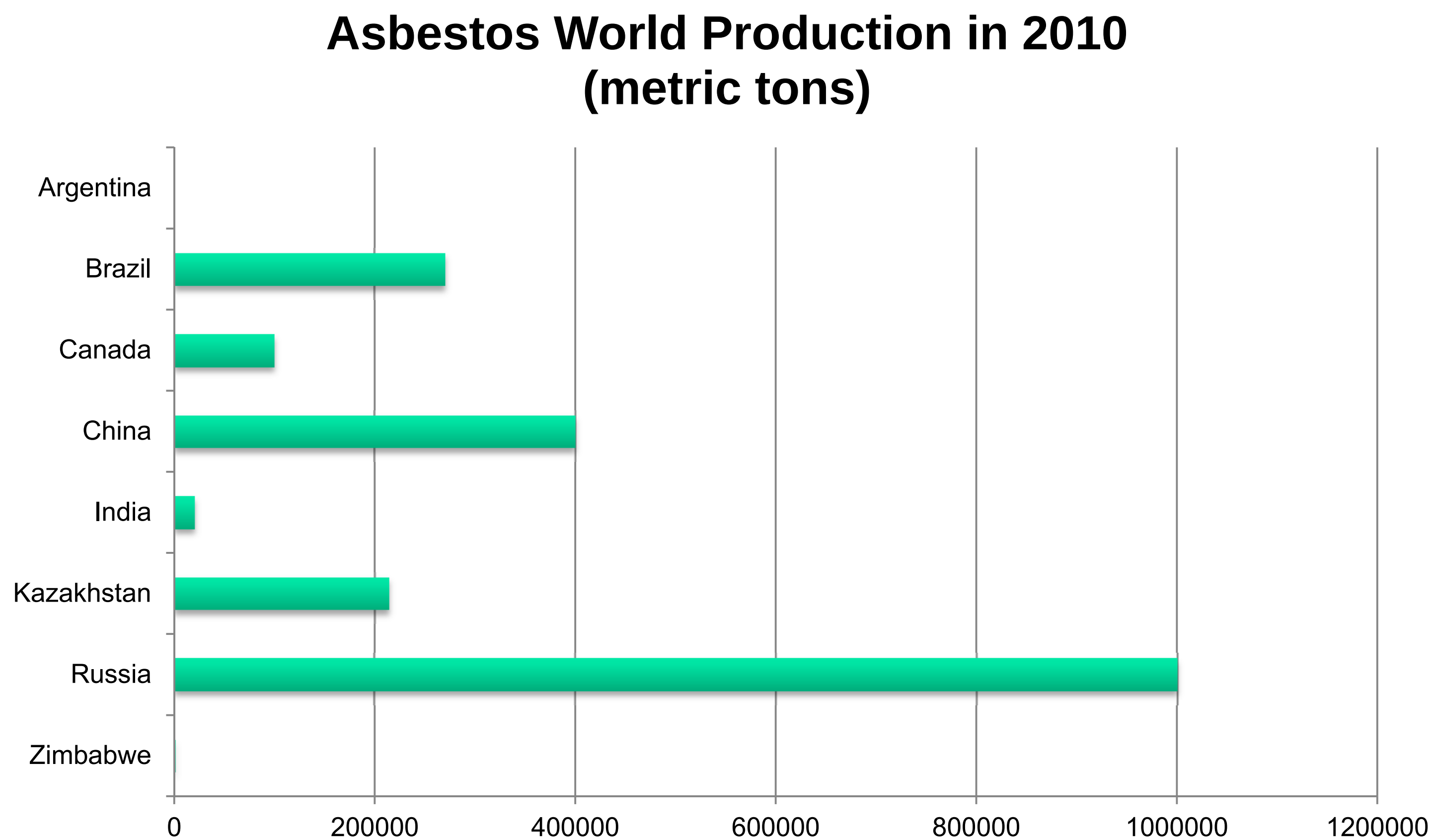
Asbestiform

Non-asbestiform

anthophyllite

tremolite

Asbestos: Current Production



Adapted from: USGS 2010 Minerals Yearbook – Asbestos (advanced release)

Asbestos Uses

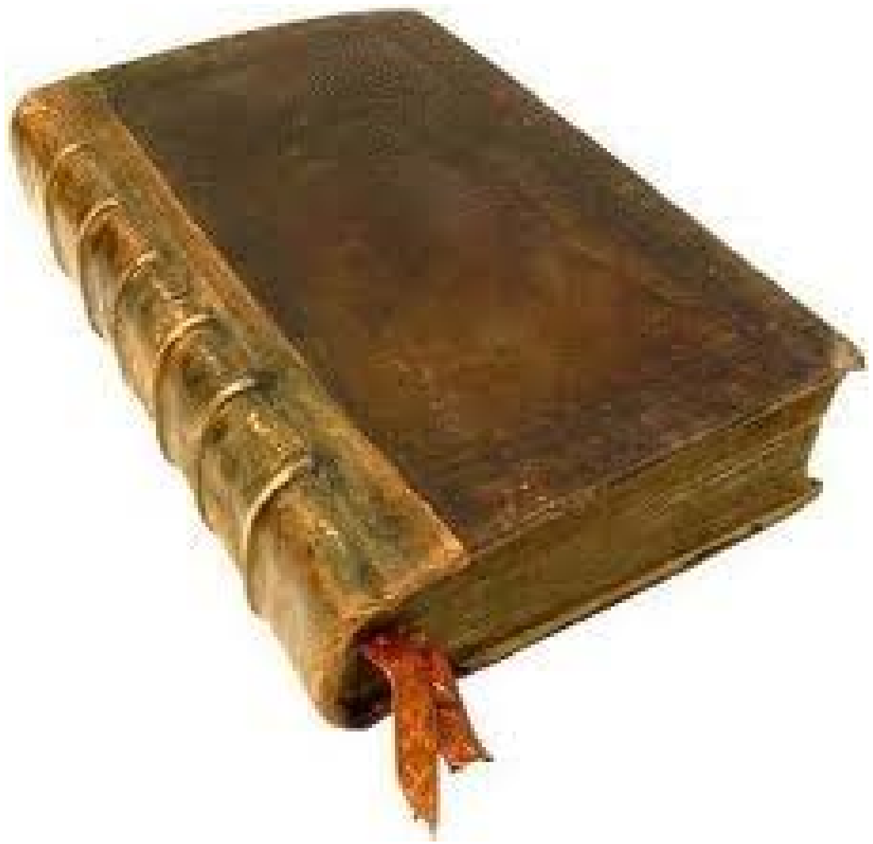
- Current uses (USGS 2010): cement products, friction products, gaskets, packing and seals, and paper and millboard
- Historical uses included 1000s of products

Historical Use Product Categories (EPA 1989)			
Asbestos-cement corrugated sheet	Asbestos-cement flat sheet	Asbestos-cement pipe	Asbestos-cement shingle
Roof coatings	Flooring felt	Pipeline wrap	Roofing felt
Asbestos clothing	Non-roof coatings	Vinyl/asbestos floor tile	Automatic transmission components
Clutch facings	Disc brake pads	Drum brake linings	Brake blocks
Commercial and industrial friction products	Sheet and beater-add gaskets (except specialty industrial	Commercial, corrugated and specialty paper	millboard
Rollboard			

Asbestos Contamination in Soil

- Poor waste management practices
- Uncontrolled building demolition
- Historical contamination is an issue
  - Better regulated now
- Friable asbestos primary concern for asbestos soil contamination
  - Potential risks from friable asbestos – asbestos that has crumbled and dispersed
  - Exposure from air pathway as asbestos particles are suspended in air and dispersed

Regulatory Environment



OSHA

- First permissible exposure limit (PEL) promulgated in 1971 (12 f/cm^3)
  - PEL reduced in 1972 (5 f/cm^3), 1976 (2 f/cm^3), 1986 (0.2 f/cm^3) and 1994 (0.1 f/cm^3)
- Definition of "asbestos"
  - Originally defined as chrysotile, crocidolite, amosite, anthophyllite, tremolite, actinolite
  - In 1992, changed to explicitly limit definition to asbestiform habit
- Applicable to "occupational exposures"
  - Separate regulations for construction workers and shipbuilding industry

EPA Laws and Regulations

- TSCA (15 U.S.C. 2601, *et seq*.)
  - Title 1 – Control of Toxic Substances - § 2605. Regulation of hazardous substances and mixtures
    - Passed in 1976
    - Not specific to asbestos
  - Title 2 – Asbestos Hazardous Emergency Response Act (AHERA)
    - Passed in 1986
    - Defines asbestos consistent with OSHA

EPA Laws and Regulations

- 40 CFR Part 763 – Asbestos
  - Subpart E - Asbestos-Containing Materials in Schools (1987)
    - Implements AHERA
    - Defines asbestos consistent with OSHA
    - Defines asbestos-containing material as >1% by weight
  - Subpart G - Asbestos Worker Protection (2000)
    - Applies OSHA standards to employees otherwise not covered

EPA Laws and Regulations

- 40 CFR Part 763 – Asbestos
  - Subpart I - Prohibition of the Manufacture, Importation, Processing and Distribution in Commerce of Certain Asbestos-Containing Products; Labeling Requirements (1989)
    - Known as the asbestos ban and phase out rule
    - Overturned by Court of Appeals in 1991
    - Limited to flooring felt; rollboard; corrugated, commercial, or specialty paper; and "new uses"

EPA Laws and Regulations

- 40 CFR Part 61– National Emissions Standards for Hazardous Air Pollutants (NESHAPS); Subpart M: National Emissions Standard for Asbestos (1973; 1990)
  - Defines asbestos and asbestos-containing material same as in AHERA
  - 40 CFR Part 61.145: Standard for Demolition and Renovation
    - Remove all regulated asbestos-containing material from a facility being demolished or renovated before beginning any activity that disturbs the material

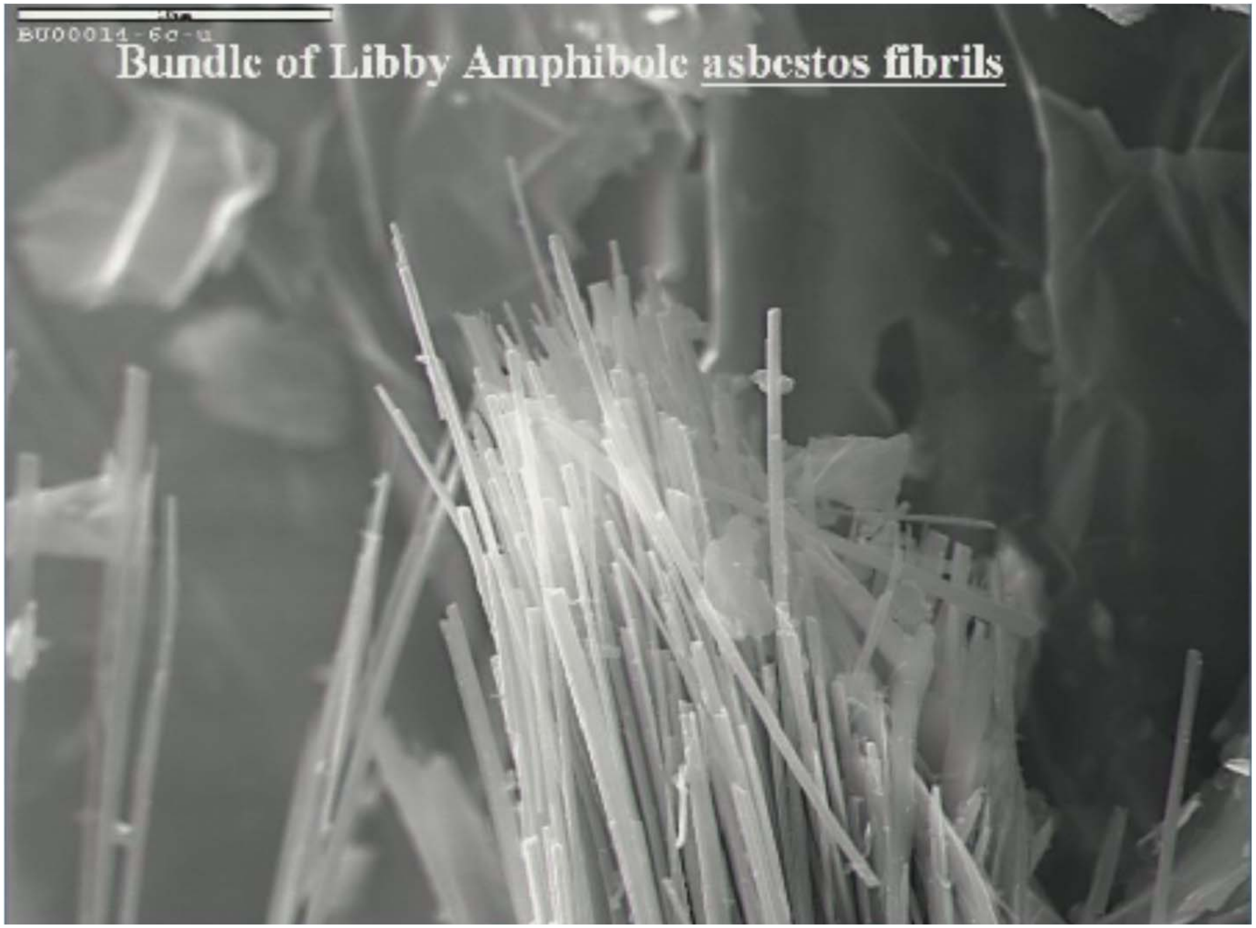
Alternative Asbestos Control Method (AACM)

- A proposed best-practice method developed by several offices within EPA, tested over several years
- Remove only accessible friable asbestos, spray with water / surfactant during and after demolition
- Intended to be comparable to NESHAPS results (remove all asbestos prior to demolition) for lower cost
- EPA Office of Inspector General issued a report in December 2011 indicating the method may threaten public health

EPA Laws and Regulations

- Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (1980)
  - Historically, asbestos addressed in Superfund based on ACM as defined in NESHAPS (> 1% by weight) and other regulatory programs
  - 2004 OSWER Directive recommended that risk-based, site-specific action levels be developed to ensure protection of public health

Sample Collection and Analysis



Asbestos Sampling by Medium

Matrix	Comments
Bulk	Generally designed for commercial-grade Asbestos Containing Materials (*not addressed here*)
Dust	Micro-vacuum; wipes (*not addressed here*)
Air	**Ambient (stationary); personal air monitoring**
Soil	**Discrete or composite soil samples, followed by separation of fibers (elutriator, fluidized bed)**

Overview of Air and Soil Sampling and Analysis Approaches

"Releasable Asbestos" sampling → Air mixing / dispersion model → Air concentration

Air sampling → Air concentration

Soil sampling → Dust resuspension model → Air mixing / dispersion model → Air concentration

Air Sampling - Stationary

- High-volume pump
- Pulls air through filter cassette
- Filter paper traps fibers and dust from the air

Personal Air Monitoring

Activity Based Air Sampling

– Based on personal air monitoring

Releasable Asbestos Field Sampler

- A method for measuring emissions of asbestos from soil disturbance

- A mathematical model for correlating results with breathing zone air for different activities is under development

Soil Sampling

- Composite over multiple locations or take discrete samples
- Need a model for correlating soil concentrations with breathing zone air

Air Sampling

- Site characterization or monitoring
  - Air integrates across space/time
  - Comparability and representativeness – EPA DQIs (reproducibility)
    - Meteorology, soil type, soil moisture content
  - Spatial considerations
    - One population
    - Clusters or patterns of contamination
  - Temporal dimensions to consider
    - Duration of project, exposure duration

Soil Sampling

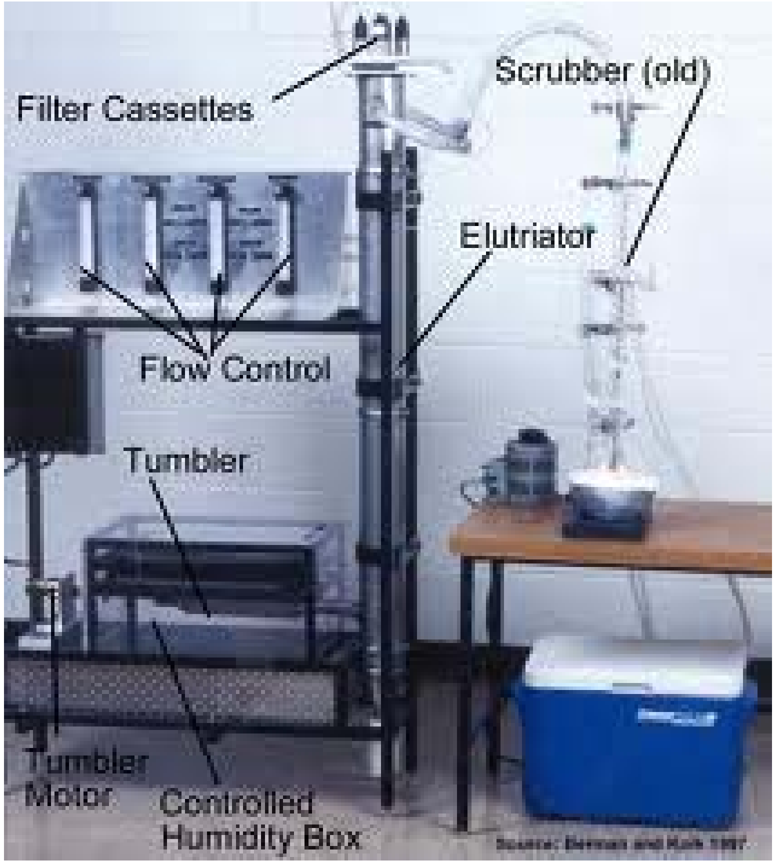
Conceptual Site Model considerations

- Spatial patterns?
  - One population?
  - Clusters of contamination?
- Temporal considerations
  - Exposure duration
- Discrete or composite samples?
  - Composite samples can lower variance
- Often take very near surface samples (2 in.)
  - Asbestos exposure is from air pathway
  - Depends on planned site use, CSM, etc.

Separating Fibers from Soil Samples

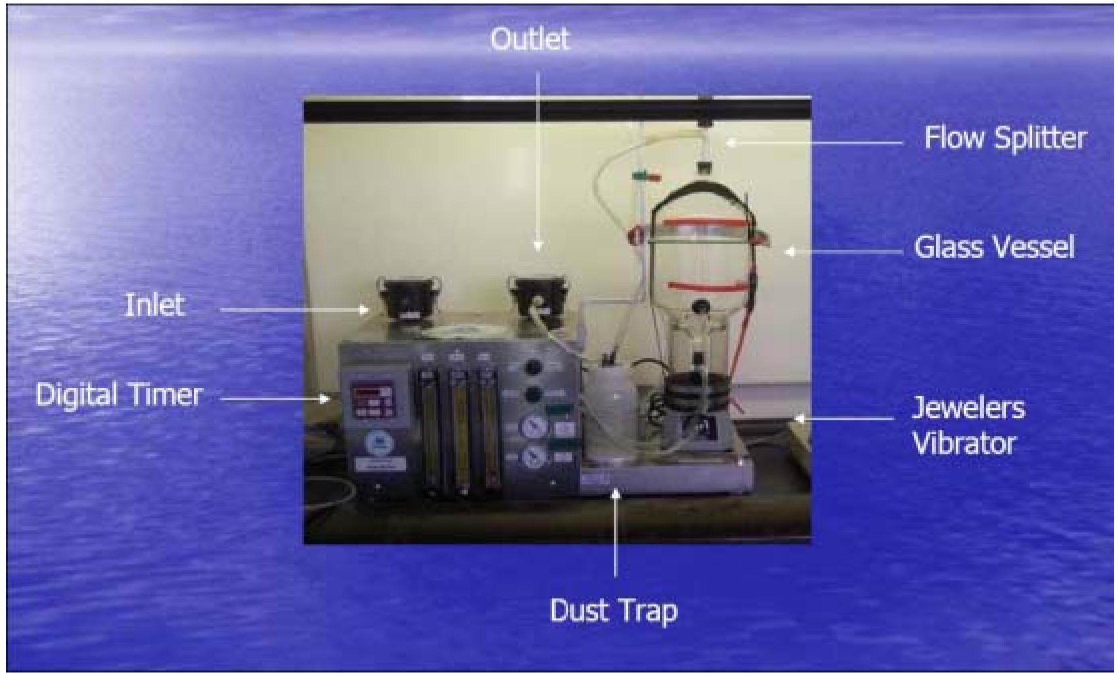
Elutriator for capturing asbestos fibers from a soil sample

Air is pulled through the tumbler and passes up through the elutriation tube – air flow rate determines particle size that can reach the filters



Separating Fibers from Soil Samples

Fluidized bed for capturing asbestos fibers from a soil sample



Air flow through the soil bed causes the soil-air mixture to behave as a fluid resulting in easy separation of fine particulates

Soil Resuspension

- Release of respirable particles (including asbestos fibers) due to wind erosion
  - Example: EPA Soil Screening Guidance (from Cowherd, 1985)

$$E_{10} = 0.036 \times (1 - v) \times \left(\frac{[u]}{u_t}\right)^3 \times f(x)$$

E_{10} = PM_{10} emission factor (g / m^2-hr)
v = fraction of vegetative cover
u = mean annual wind speed
u_t = threshold value of wind speed at 7 m
F(x) = empirically-based function related to u and u_t

Soil Resuspension and Dispersion

- Release of respirable particles (including asbestos fibers) due to vehicle traffic on unpaved roads
  - Example: EPA AP-42 (Compilation of Air Pollutant Emission Factors; Ch. 13, unpaved roads)

$$E = \frac{k \times (s/12)^{a} \times (S/30)^{d}}{(M/0.5)^{c}}$$

E = emission factor (lb / vehicle mile traveled)
s = surface material silt content (%)
S = mean vehicle speed
M = surface material moisture content (%)
k, a, c, d = empirical constants tabulated in AP-42

Air Dispersion

- Breathing zone concentrations in the impacted area
  - Example: EPA Soil Screening Guidance (based on Industrial Source Complex modeling)

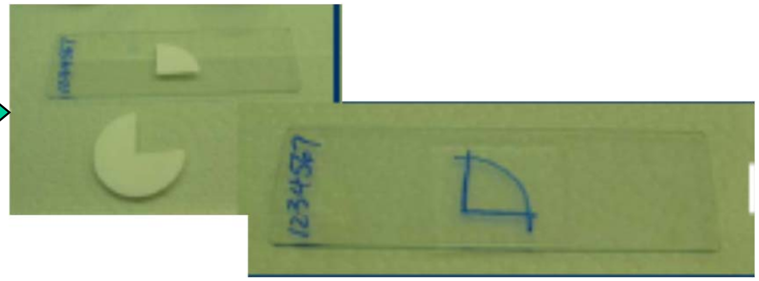
$$Q/C_{wind} = A \times exp\left[\frac{(lnA_{site} - B)^2}{C}\right]$$

Q/C_{wind} = inverse of mean PM_{10} concentration above the site per unit PM_{10} flux (g / m^2-sec per kg/m^3)

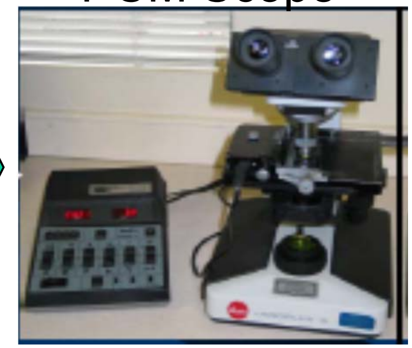
A_{site} = area of site (acres)

A, B, C = curve fitting constants tabulated in EPA's Soil Screening Guidance

Air Filter Preparation

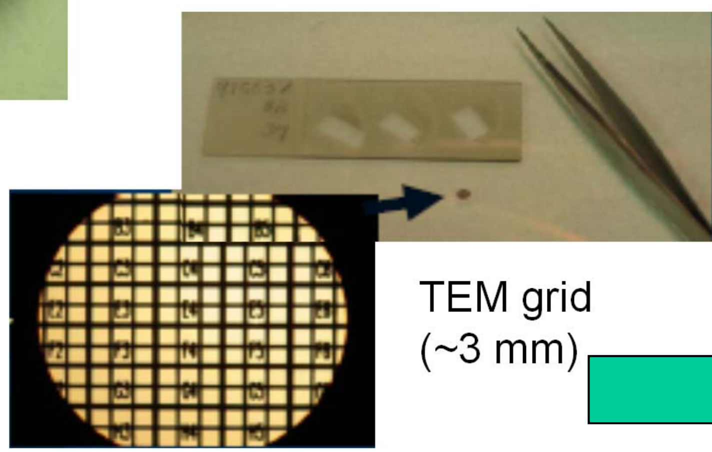


PCM Scope



PCM slide – ¼ of filter
(25 mm filter)

TEM Scope



TEM grid
(~3 mm)

Air Filter Asbestos Analysis

- Phase Contrast Microscopy
  - Approximately 400x magnification
  - Light scattered by small particles is caused to interfere with unscattered light, enhancing the visibility of very small particles
- Transmission Electron Microscopy (TEM)
  - Up to 40,000x magnification
  - Higher resolution due to the much smaller wavelength of electrons compared to photons

PCM Analysis

- Fibers thinner than about 0.25 – 0.5 μm cannot be seen
- Asbestos fibers and non-asbestos fibrous particles such as fiberglass, cellulose, and gypsum cannot be distinguished
- **Problem:** The fibers counted might not be asbestos, and the fibers *not* counted might be asbestos

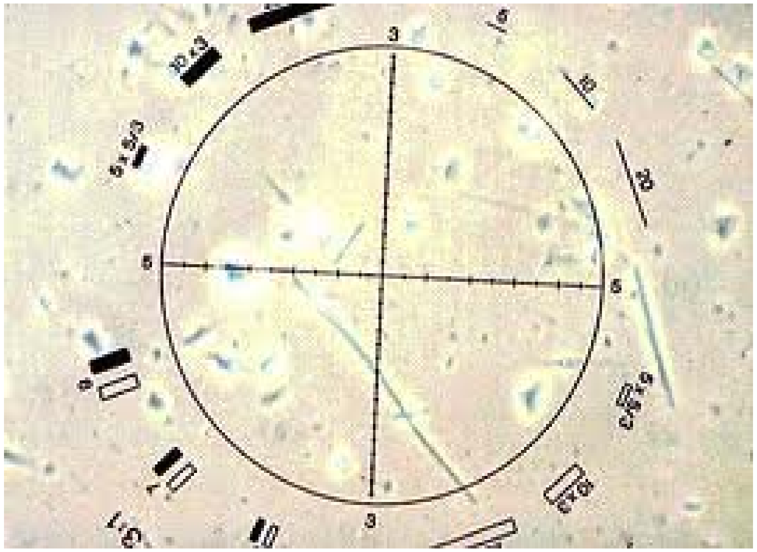
TEM Analysis

- Can distinguish between asbestos fibers and non-asbestos fibers
- Can distinguish among the different types of asbestos fibers
- Because of it's higher resolution, fibers not visible with PCM can be counted

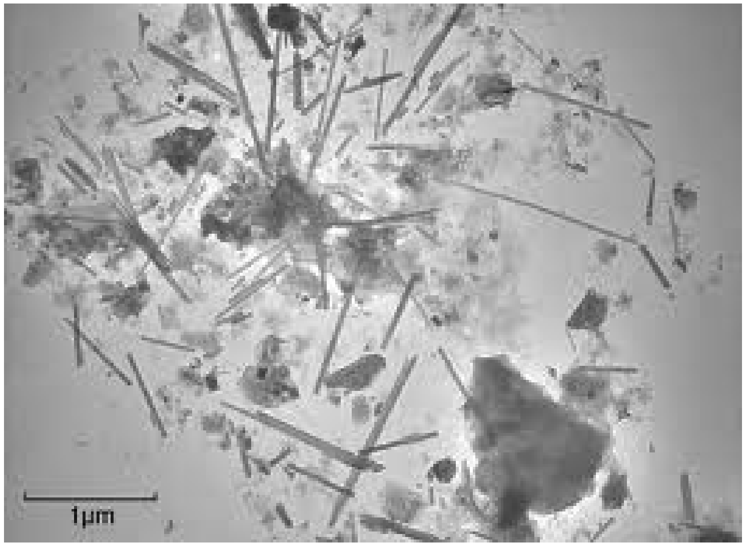
PCM vs. TEM Analysis

TEM can resolve high fiber aspect ratios such as 100:1– even at lengths approaching 1 µm; whereas PCM would require a length of 25 – 50 µm

PCM analysis
tic marks at 3 and 5 µm



TEM analysis; Chrysotile



PCM vs. TEM Analysis

- PCM asbestos measurements do not correlate with higher-resolution TEM measurements
- The differences in resolution are such that they reveal different components of a sample

What is PCMe?

- PCM-equivalent, a way of using TEM analysis to emulate PCM analysis
  - Fibers are counted or reported in two ways following TEM analysis
    1. Including shorter and/or thinner fibers not visible by PCM and
    2. Counting only fibers longer than 5 µm, aspect ratio of 3:1 or higher, and width between 0.25 and 3.0 µm

Why Does PCMe Exist?

- Counting taking advantage of TEM resolution allows full characterization of asbestos forms (chrysotile and various amphiboles) and thin fibers to support future analyses in the event toxicity models are revised

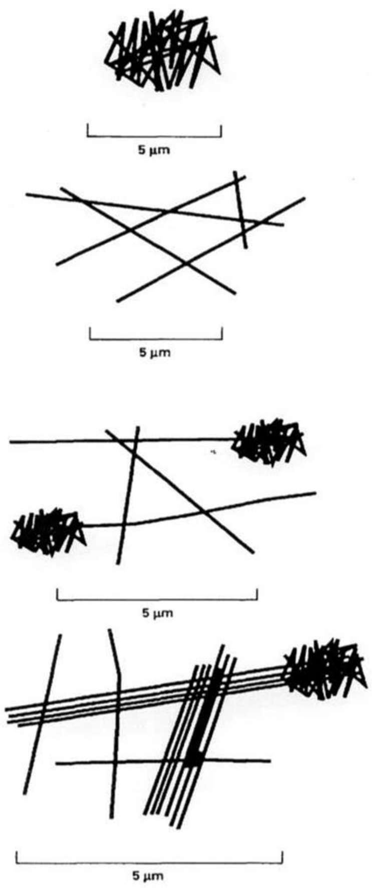
- Counting as PCMe is consistent with the current EPA toxicity model (IUR) which was derived based on dose-response studies that employed PCM air measurements. But unlike PCM, counting can be limited to just asbestos fibers

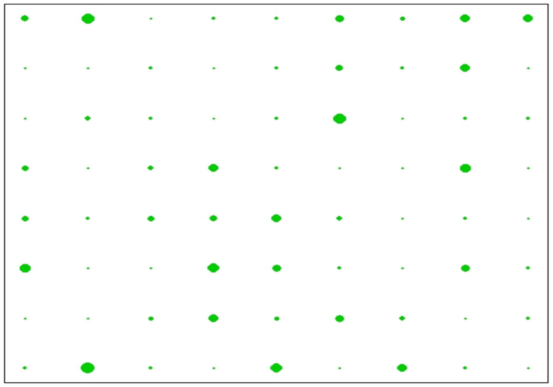
Basis of PCM and PCMe Fiber Counting Rules

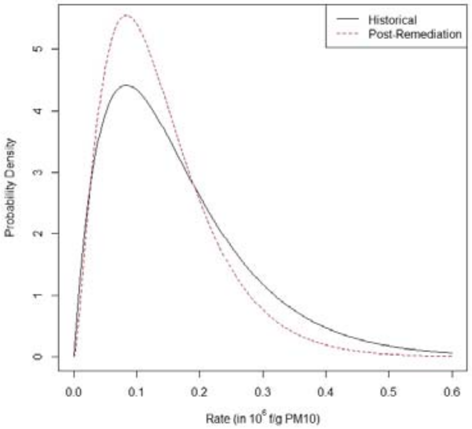
- Fiber counting protocols (length, width, and aspect ratio) have their basis in EPA's 1986 IUR for asbestos and related analytical methods; NIOSH 7400 (PCM) and ISO 10312 or NIOSH 7402 (TEM)

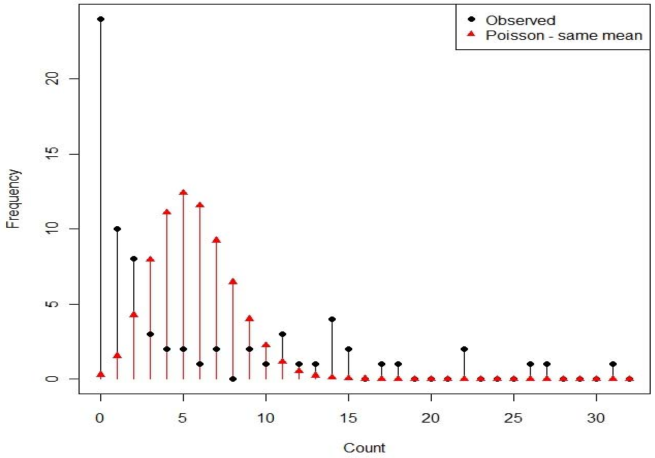
- The epidemiological studies used by EPA to develop the IUR value in 1986 examined incidence and mortality of lung cancer and mesothelioma in relation to workplace asbestos air samples analyzed by PCM

Fiber Counting & Statistical Methods









Fiber Counting & Statistical Methods

- Difficulty of counting asbestos fibers
- Statistical approach to reported counts
  - Sample design (Data Quality Objectives – DQOs)
  - Statistical analysis of asbestos data
- Asbestos detection limits?

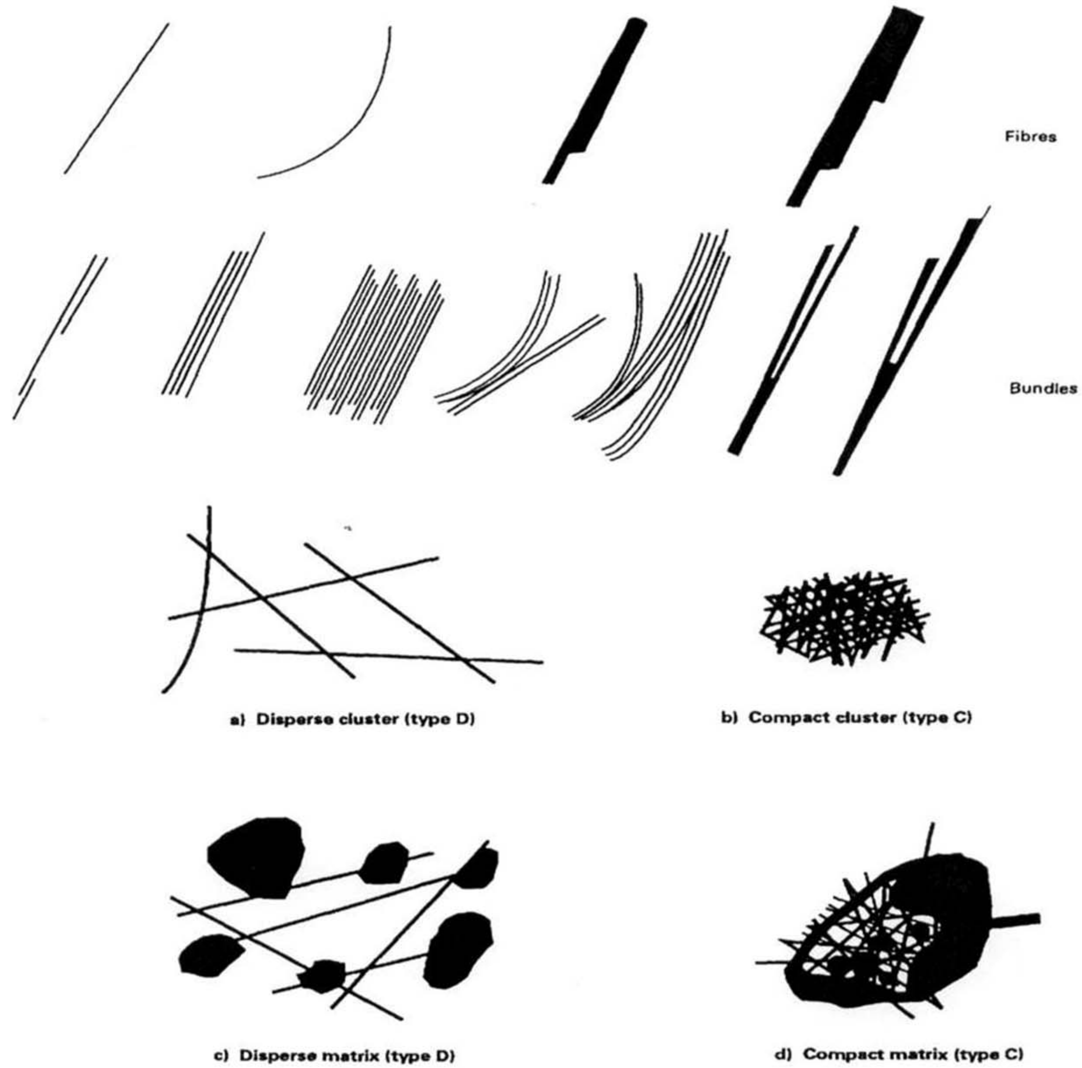
Asbestos Structures (ISO 10312)

Fibers

Bundles

Dispersed and Compact Clusters

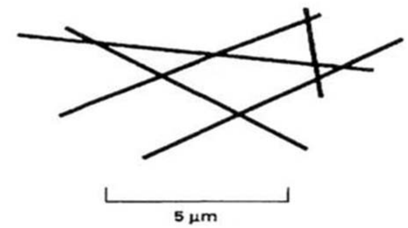
Dispersed and Compact Matrices



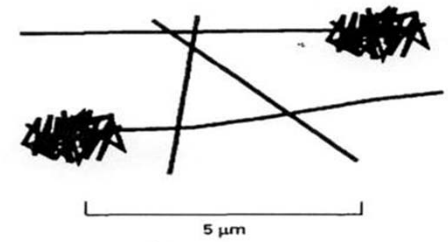
ISO Counting Asbestos Structures

compact cluster with more than 9 fibers all < 5 µm

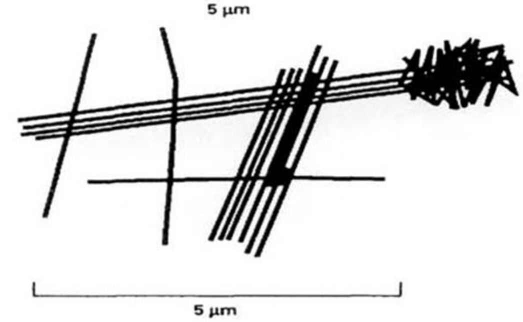
dispersed cluster with 5 fibers, 4 of which > 5 µm



dispersed cluster with 4 fibers, 2 are > 5 µm, 2 cluster residuals with more than 9 fibers



dispersed cluster with 3 fibers, 2 bundles, 1 is > 5 µm, and 1 cluster residual with more than 9 fibers

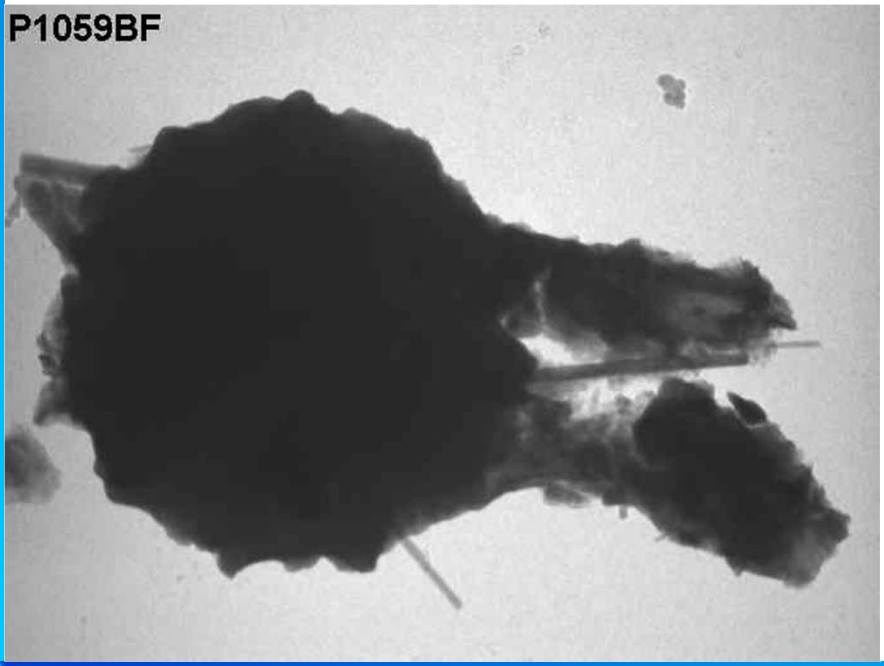


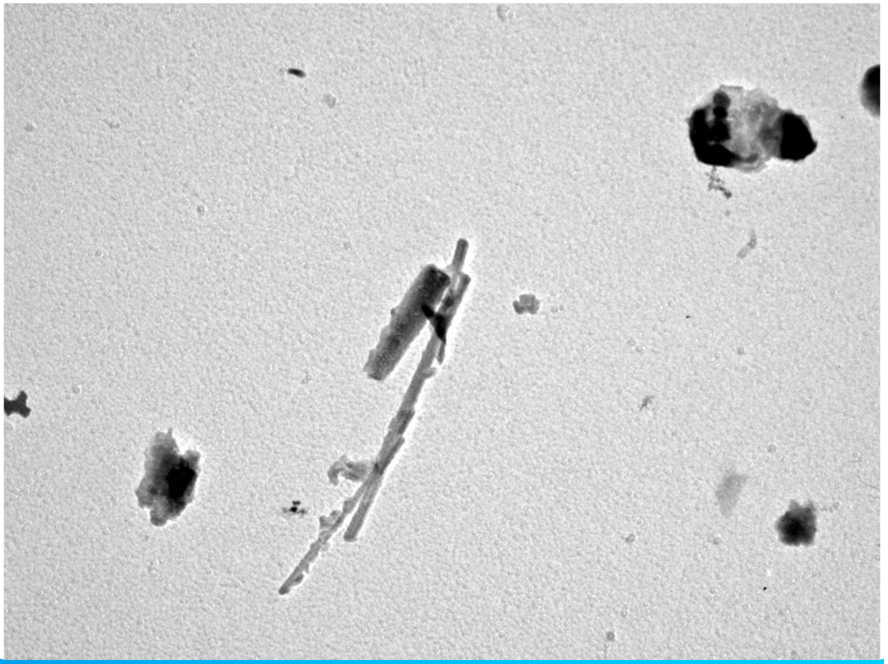
ISO Counting Asbestos Structures

- Fibers, bundles, clusters, or matrices can be reported as asbestos structures
- ISO counting rules do not allow reporting of more than 9 “fibers” for a single structure
  - This seems to be more to do with available room on the reporting form than any other reason!
- Counting issues at this level have been largely ignored, but might have an effect on risk assessment
  - For example, do bundles pose greater risk than fibers?

Counting Asbestos Structures

- Complex clusters and matrices can be difficult to count
- Labs report primary structures and secondary structures
  - Could be both chrysotile and amphibole





Counts to Concentration

- Obtain total number of asbestos fibers counted in viewed grid openings, x
- Translate to fibers per area of filter, x_A
  - Filters are typically about 385 mm^2, A_f
  - Filters typically are viewed through some small number of grid openings, n_g
  - Each grid opening is typically about 0.01 mm^2, A_g

$$x_A = \frac{x \times A_f}{n_g \times A_g}$$

Counts to Concentration

- To translate to a concentration, C, need the volume or mass of medium sampled, M
- Air: M = volume (cm^3) of air sampled (from air flow rate and time)
- Soil: M = mass (g PM10) of respirable dust collected on the filter

$$C_M = \frac{x \times A_f}{n_g \times A_g \times M}$$

Analytical Sensitivity

- The analytical sensitivity, *AS*, for a specific sample can be extracted from the concentration formula:

$$AS = \frac{A_f}{n_g \times A_g \times M}$$

- Concentration can be expressed more simply as:

$$C_M = x \times AS$$

Pooled Analytical Sensitivity

- Analytical sensitivity is defined above for one sample
- Application to more than one sample simply requires attention to the total filter area and total volume or mass of sample material (*n* is the number of samples)

$$Pooled\ AS = \frac{1}{\sum_{i=1}^{n} \frac{1}{AS_i}}$$

- If AS_i is the same for all samples, then this is simply:

$$Pooled\ AS = \frac{AS_i}{n}$$

Sensitivity – Balancing Act

- The lower the analytical sensitivity, the fewer samples are needed
- However, greater analytical sensitivity comes at a cost – so, there is a trade-off

Volume of Air (Liters)	# Grid Openings	Sensitivity (S/cc)	Approx. Cost
2,500	10	0.0012	~$80
2,500	30	0.0004	~$280
2,500	50	0.0002	~$480

Many samples

- For risk assessment a mean concentration across samples is usually required
  - Or an upper confidence limit of the mean (UCL)
- How do we get there for asbestos?
- Asbestos concentrations are based on counts
- Count data are often modeled using the Poisson distribution:

A discrete probability distribution that expresses the probability of a given number of events occurring in a fixed time or space

Application of Poisson to Asbestos

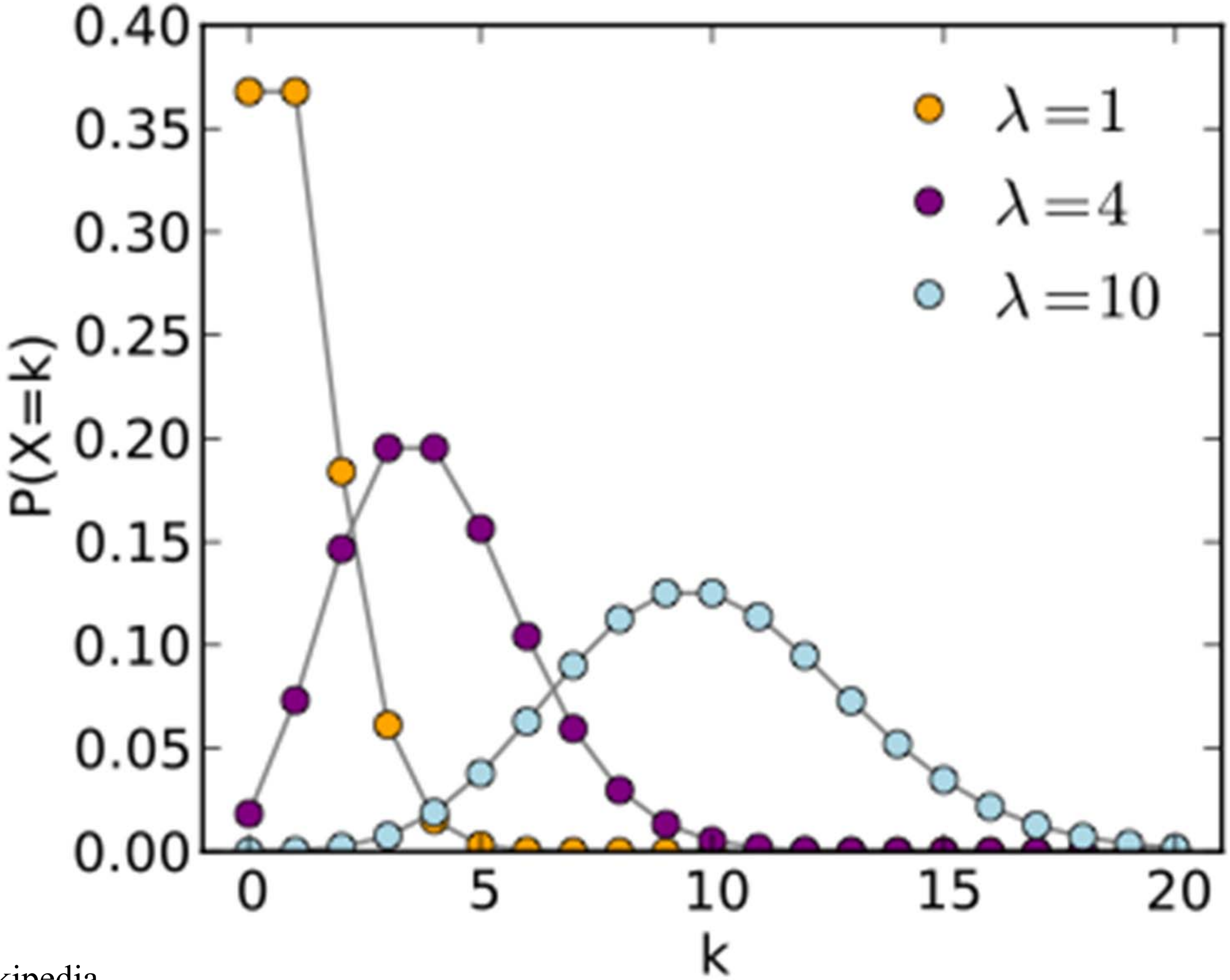
The probability of a given number of asbestos structures of interest occurring in a sample (air or soil)

•If the expected number of asbestos structures in a sample is λ, then the probability that there are exactly *x* asbestos fibers is equal to:

$$P(x;\lambda) = \frac{\lambda^x e^{-\lambda}}{x!}$$

•E.g., if we expect to see, on average, **1 structure per sample,** then the probability of actually seeing (0, 1, 2, 3) **structures in a sample** is (0.37, 0.37, 0.18, 0.06)

Poisson Distributions



Source: Wikipedia

Interesting Poisson Properties

- Mean = variance
- Mode is the nearest integer less than the mean
- Independent Poisson's add:
  - So the Poisson distribution applies to individual samples and all samples together

$$Y = \sum_{i=1}^{n} X_i \sim Poisson\left(\frac{\lambda}{Pooled\ AS}\right)$$

Poisson and Analytical Sensitivity

- *AS* can be used directly in the Poisson formulation for asbestos structure counts
  - Given laboratory reporting, this is convenient:
- This is a *Poisson process* with rate λ / *Pooled AS*
  - Makes sense – we should expect to see more total fibers in more samples
- The Poisson grand mean is estimated as the number of fibers observed in all samples together
- Concentration is the *mean* $\times$ *Pooled AS*

= (total number of fibers / total volume or mass)

Seems reasonable !

Upper Confidence Limits

- Poisson distribution theory can be used to calculate a mean or a UCL across samples
- Assumes counts in each grid opening are Poisson
- Assumes all grid openings are independent
  - Including that the filter is uniformly populated
  - So that Poisson addition can be performed

Poisson Means and UCLs

- Formula is not pleasant
  - Simple to compute however
- Relies on relationship of the Poisson and Gamma distributions

# fibers	0	1	2	3	5	10	20	50
UCL	3.00	4.74	6.30	7.75	10.5	17.0	29.1	63.3

Poisson UCLs

- Dissatisfaction with the UCL when a low count is observed has led EPA to prefer direct use of the mean
- But that has its own problems – DQOs cannot be applied (uncertainty has been eliminated) and RAGs requires estimates of RME for risk assessment (RAGs suggests 95% UCLs)
- Instead of avoiding the problem, we can investigate other statistical approaches – there are better statistical methods….

Bayesian Interpretation of Poisson UCLs

- The UCL has an interpretation in Bayesian statistics:

The UCL corresponds to prior understanding (DQOs?) that there is 1 fiber in an infinitesimally small sample

- This does not make much sense !
- This understanding is sometimes referred to as a "non-informative" prior opinion
- It seems unlikely that a DQO process would support this prior view

Another UCL Option

- There is another common “non-informative” prior
  - “Jeffrey’s prior” corresponds to a prior understanding that there are 0.5 fibers in an infinitesimally small sample
  - Bayesian UCL for this is 1.5 (instead of 3)
  - But still does not make much sense
- Better, use some prior information!

Informative Priors

- Various methods exist for constructing priors
- Idea is to utilize *all* available information
  - Site history
  - Previous data collection efforts
  - Remediation effects
- Reach agreement amongst stakeholders regarding information
- For example, after cleanup, for verification sampling, we know something already

Bayesian Examples

- Example 1 – Site characterization
  - Prior information equivalent to 2 fibers in 2 samples
  - Collect data – observe 10 samples with 0 fibers
  - Bayesian UCL is now 0.4
- Example 2 – Post-remediation
  - Prior information equivalent to 2.5 fibers in 12 samples
  - Collect data – observe 6 samples with 0 fibers
  - Bayesian UCL is now 0.3

Comparison of Sample Sizes Required

- Apply the DQO Process
- Suppose that a risk threshold will be exceeded if a 95% UCL > $0.25 \cdot 10^6$ f/g PM10 (null hypothesis)
- Allowing for a few fibers to be observed, the sample size required to pass the risk threshold:

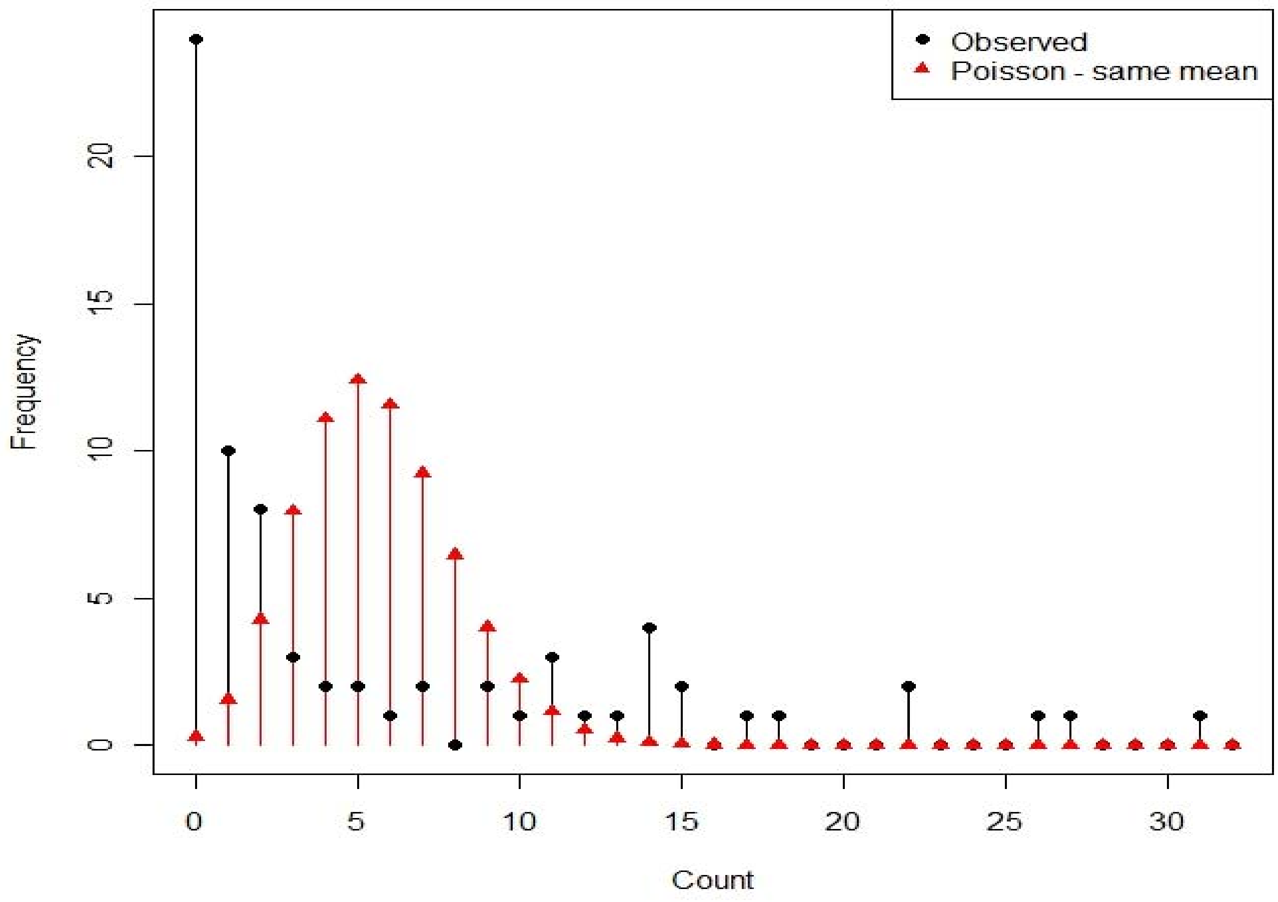
# Fibers Observed	Classical UCL	Jeffrey's	Informative Site Char.	Informative Post-Remed.
0	12	8	7	5
1	19	16	14	11
2	26	23	20	16
3	32	29	25	22
4	37	34	31	27
5	43	40	36	32

Other Prior Considerations

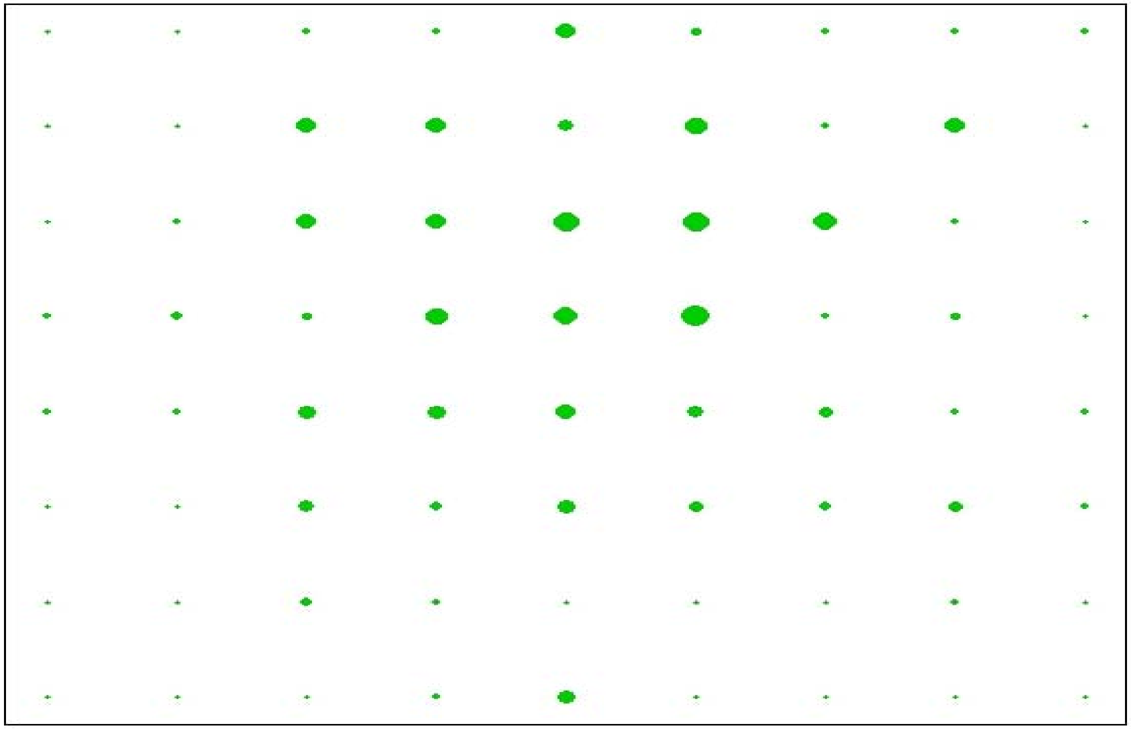
- There are other other potential issues that could be considered depending on the CSM
  – Spatial patterns, clustering
- The Poisson distribution does not always fit low count data collected from across a site
  – For example, the Poisson mode must be the largest integer less than the Poisson mean
  – Can cause over-estimation of asbestos related risk

Lack of Fit Example

n = 73, total structures = 385 : Mean > 5, Mode = 0

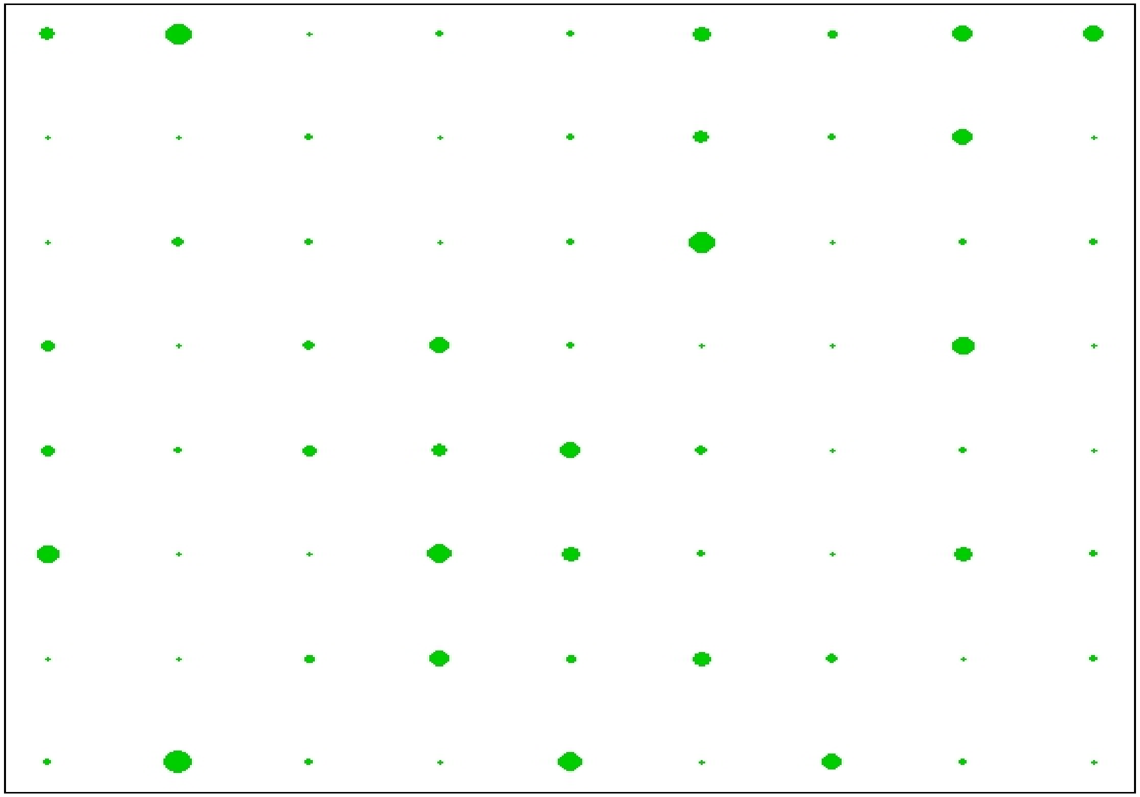


Spatial Clustering



Perhaps use Poisson clustering, or split area into separate decision units or exposure areas if possible (contaminated area and background area)

Random Contamination



Perhaps use a Poisson mixture model to account for the apparent contamination mixed with background

Statistical Issues

- For contaminated sites this does not matter
  - Normal approximation can be applied
  - Site will drive an unacceptable risk anyway
- Low counts of asbestos can cause an unacceptable risk (depends on risk scenario)
  - Use appropriate statistical models to avoid estimates of risk that are unreasonably high
- Take advantage of prior knowledge (CSM)
  - By using a Bayesian approach
    - Really not that difficult
    - Can also include value judgments (DQO-like)

Possible Solutions to Statistical Issues

1. Bayesian approach
   - avoids the use of conservative UCLs when there is prior knowledge of little or no asbestos contamination (e.g., post-remediation)
   - EPA instead suggests use of the mean, but that has its own problems – DQOs cannot be applied (uncertainty has been eliminated) and RAGs requires estimates of RME for risk assessment (RAGs suggests 95% UCLs)
2. If necessary, develop statistical models that fit the data to avoid conservative estimates of asbestos related risk
   - including Poisson clustering and mixture models

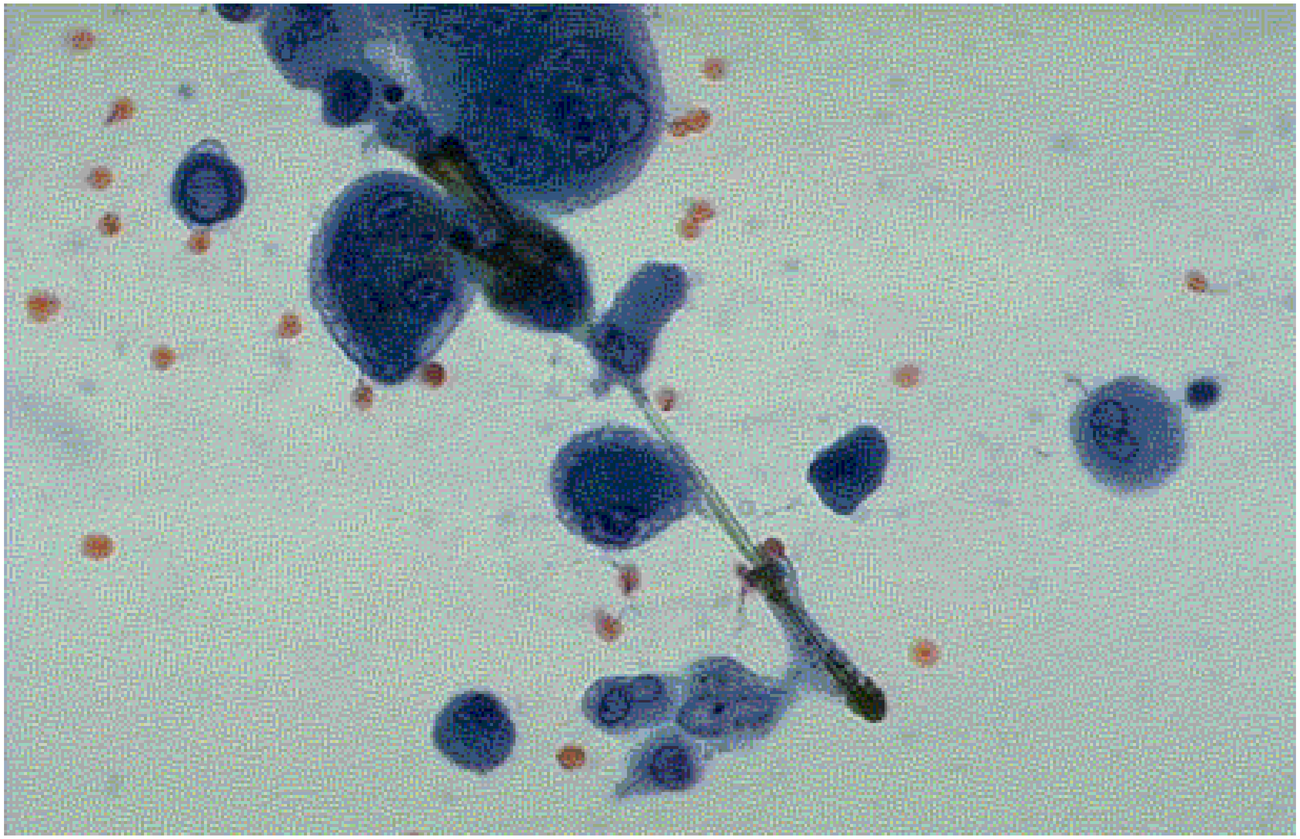
Asbestos Detection Limits?

- A Detection Limit has been proposed of 3 structures per sample
  - Based on the UCL calculation
- DLs are often reported for each sample in laboratory reports
- If applied to 20 samples all of which report 0 fibers, the sum of UCLs would be 60 fibers
  - What sense does this make?

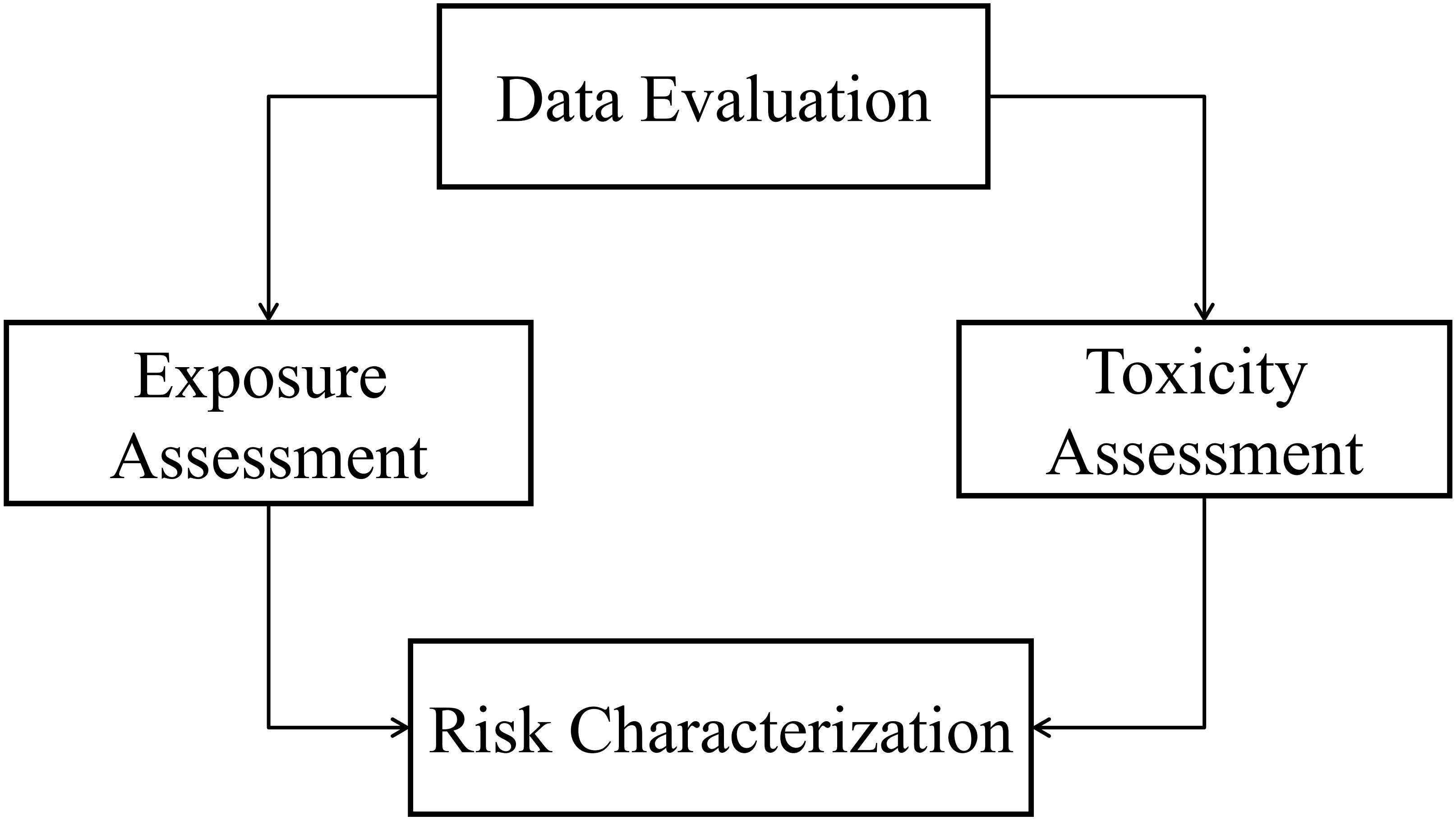
Detection Limits?

- Since the derivation is based on Poisson assumptions, the approach could be applied to each grid opening
  - Poissons add, and by extrapolation, each grid opening is Poisson !
- It is also a 95% UCL – unusual for a DL
- For count data such as these, there is no need for a DL – either asbestos fibers are observed or they are not

Asbestos Risk Assessment: Principles and Methods



Risk Assessment Process



EPA RAGS Part A (1989)

Risk Assessment Process

- Data Evaluation
  - Analyze site characteristics and site analytical data to identify data of sufficient quality for inclusion in risk assessment
  - Based on these data, identify chemicals of potential concern (COPCs)

Risk Assessment Process

- Exposure Assessment
  - Measuring or estimating the intensity, frequency, and duration of exposure to COPCs
  - Exposure occurs via “complete” exposure pathways
    - Source/mechanisms for release
    - Transport medium (e.g., air, water, soil)
    - Point of contact with medium
    - Exposure route at contact point (e.g., inhalation, ingestion, dermal contact)

Risk Assessment Process

- Toxicity Assessment
  – Hazard identification (potential for chemical to cause adverse health effects)
  – Dose-response assessment (relation between extent of exposure and increased likelihood of adverse effects)
    - Toxicity criteria (e.g., cancer slope factor)

Risk Assessment Process

- Risk Characterization
  - Exposure and toxicity assessments integrated into quantitative or qualitative estimates of potential health risks
    - Excess cancer risks
    - Noncancer hazards
  - Uncertainty assessment

Estimating Risk for Chemicals

Risk = Exposure × Toxicity

For inhalation:

- "Exposure" includes
  - Air Concentration (e.g., $\mu g/m^3$)
  - Time (hours/day, days/year, years)
- "Toxicity" includes
  - Reference concentration (RfC) for noncarcinogens (e.g., $\mu g/m^3$)
  - Inhalation Unit Risk (IUR) for carcinogens [e.g., $(\mu g/m^3)^{-1}$]

Estimating Risk for Chemicals

- For noncarcinogens

$$HQ = \frac{[Air] \times ET \times EF \times ED}{AT} \div RfC$$

$$= \frac{\mu g/m^3 \times \text{hours/day} \times \text{days/year} \times \text{years}}{\text{hours}} \div \mu g/m^3$$

- For carcinogens

$$Risk = \frac{[Air] \times ET \times EF \times ED}{AT} \times IUR$$

$$= \frac{\mu g/m^3 \times \text{hours/day} \times \text{days/year} \times \text{years}}{\text{hours}} \times (\mu g/m^3)^{-1}$$

Estimating Risk for Asbestos

Risk = Exposure x Toxicity

$= [\mathrm{Air}] \times \mathrm{ET} \times \mathrm{EF} \times \mathrm{IUR}$

$= \mathrm{f/cm^3} \times \mathrm{hour/hour} \times \mathrm{day/day} \times (\mathrm{f/cm^3})^{-1}$

For asbestos, ED is incorporated into the IUR because the duration of exposure and age at first exposure affects cancer risk

Exposure/Toxicity Metric

- For chemicals, [Air] and IUR in units of mass per air volume (e.g., $\mu g/m^3$)
- For asbestos, [Air] and IUR in units number of fibers per air volume (e.g., f/cm^3)
  - But the "f" in f/cm^3 will vary depending on analytical method and counting rules

Options for Air Concentrations

- Direct measurements of asbestos concentrations in air
  - e.g., "activity-based sampling" (ABS) of breathing zone concentrations
- Modeled estimates of asbestos concentrations in air based on measured concentrations in soil
  - e.g., Soil sampling followed by modeling of breathing zone concentrations

Activity-Based Sampling

- Pros
  - Direct measurement of asbestos air concentration in breathing zone
  - Measurement techniques well established
  - Different (and divergent) activities can be evaluated (gardening, child play, running, bicycle or motorcycle riding)
  - EPA has developed sampling protocols for several activities
- Cons
  - Difficult to capture intra-individual and inter-individual variability
  - Difficult to control environmental variability (soil moisture content, wind, etc)
  - Reproducibility

Modeled Estimates from Measured Soil Concentrations

- Pros
  - Able to evaluate more scenarios/situations/activities than can be practically measured
  - Soil samples can be collected across a wide area, thereby better representing source concentrations
- Cons
  - Uncertainties associated with all models
  - Measurement techniques less well established

IRIS IUR Definition of Fibers

- EPA IRIS IUR = 0.23 $(f/cm^3)^{-1}$
  - IRIS: Integrated Risk Information System
  - Combined risk for lung cancer and mesothelioma
  - Based on PCM measurements of air samples (fibers >5 μm in length and >0.4 μm in width, with an aspect ratio of ≥3:1)
  - Assumes lifetime exposure (24 hours/day, 365 days/year, for 70 years)

EPA Superfund Asbestos Framework Definition of Fibers

- Provides range of IURs depending on age of first exposure and ED
  - Starting point is IRIS IUR (combined risk of lung cancer and mesothelioma) for lifetime exposure
  - Based on TEM measurements of PCMe fibers (>5 µm in length, between 0.25 and 3 µm in width, with an aspect ratio of ≥3:1)

EPA Framework (2008)

Risk = [Air] x TWF x IUR

Where:

[Air] = PCMe fibers/cm^3 based on modified ISO 10312 analytical method

TWF = time weighting factor (hr/hr x day/day)

IUR = IRIS IUR for lifetime exposures;
IUR_{LTL} from table for <lifetime exposures

EPA Framework (2008)

Exposure Scenario	Hours per day	Days per year	Time Weighting Factor (TWF)
Continuous	24	365	1
Baseline Residential	24	350	0.96
Gardening	10	50	0.057
Recreational	1	156	0.018
Child playing in soil	2	350	0.080

Adapted from Table 1

Effect on estimated risk is linear (decrease TWF by factor of 2 and risk is decreased by factor of 2)

EPA Framework (2008)

Age at first exposure (years)	Exposure Duration (years)									
	1	5	6	10	20	24	25	30	40	LT
0	0.010	0.047	0.055	0.085	0.14	0.15	0.16	**0.17**	0.19	**0.23**
1	0.099	**0.045**	0.053	0.081	0.013	0.015	0.15	0.17	0.19	
5	0.0085	0.039	0.046	0.070	0.11	0.13	0.13	0.14	0.16	
10	0.0070	0.032	0.038	0.057	0.092	0.010	0.10	0.11	0.13	
20	0.0049	0.022	0.026	0.039	0.062	**0.068**	0.069	**0.075**	0.083	
30	0.0034	0.015	0.018	0.026	0.040	0.044	0.045	0.048	0.052	

Adapted from Table 2 (values from Table E-4)

Effect on risk is nonlinear

EPA Framework (2008)

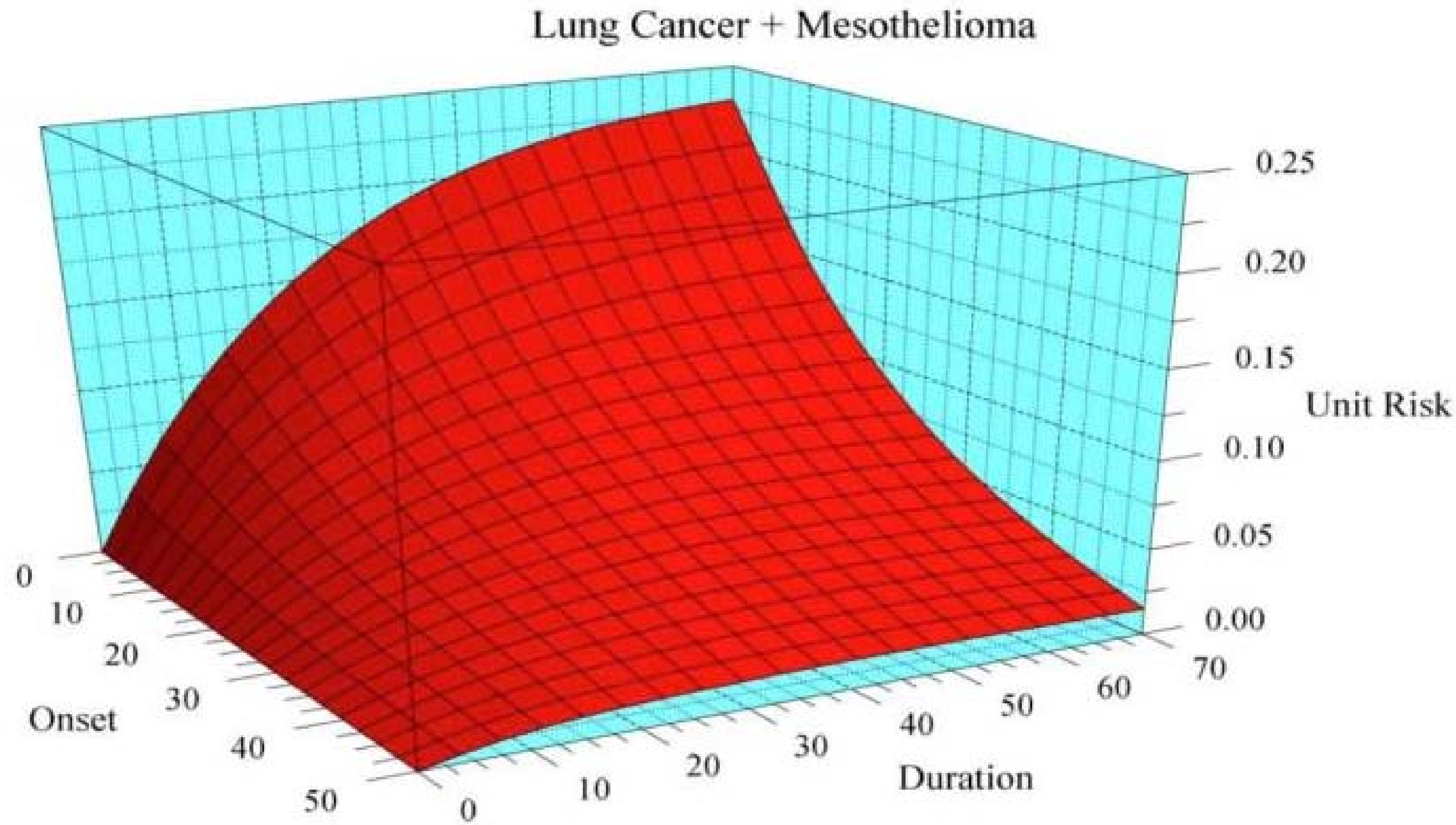


Figure 3-1

Berman and Crump (2003) Fiber Definition and Potency

- Berman & Crump (B&C, 2003) Protocol
  - Combined risk of lung cancer and mesothelioma
  - Separate IURs for chrysotile [0.057 $(f/cm^3)^{-1}$] and amphiboles [6.3 $(f/cm^3)^{-1}$] assuming lifetime exposure for a general population of smokers and non-smokers
  - Based on TEM measurements (>10 µm in length and <0.4 µm in width)

Berman & Crump Updates

- More recent work by Berman & Crump and Berman continues to refine the exposure metric:
  - Berman & Crump 2008
    - "Thin" metric – >10 µm in length and <0.4 µm in width
    - "All widths" metric – >10 µm in length and ≤3 µm in width
  - Berman 2010
    - >20 µm in length and <1.5 µm

EPA Framework vs. Berman and Crump: Fibers and IUR

EPA FRAMEWORK	BERMAN and CRUMP
IUR based on epidemiology available at time of 1986 report	IURs based on epidemiology available in 2003, 2008, and 2010
TEM analysis metric for PCMe (>5 µm in length, between 0.25 and 3 µm in width, with an aspect ratio of ≥3:1)	TEM analysis metric for protocol structures (>10 and <0.4 µm, >10 and ≤3 µm, possibly >20 µm and <1.5 µm)
One IUR value for all fiber types	Different IUR values for chrysotile and amphiboles for each metric; chrysotile about 100x less potent
PCMe metric (width 0.25 – 3 µm) applied with IRIS IUR (width >0.4 µm); some inconsistency	Exposure metrics and IUR values are paired

Non-Cancer Asbestos Toxicity

- A toxicity assessment for Libby, MT amphibole asbestos was developed in 2011 by EPA that includes non-cancer as well as carcinogenic effects
- The draft reference concentration for non-cancer effects is 0.00002 f/cc
  - Toxicity endpoint is localized pleural thickening, based on a study of workers
  - Uncertainty factor of 100

Asbestos Risk Assessment: Example

EPA Framework (2008) vs. B & C (2003) Asbestos Risk

- Soil samples collected from four properties in southern Nevada
- Soil samples analyzed by TEM; fiber counts reported for PCMe fibers and Berman (2003) fibers
- Models used to estimate air concentrations
- Estimated cancer risk for a resident based on IRIS and Berman (2003) IURs for continuous lifetime exposure

Asbestos Fiber Count Soil Data

Property	No. of Samples	Pooled AS (10^6 f/ g PM_{10})	EPA PCMe	B&C Amphibole	B&C Chrysotile
1	42	0.071	22	0	25
2	42	0.070	90	1	29
3	8	0.373	7	0	6
4	8	0.373	4	0	0

Adapted from NDEP 2011, Appendix C, Table 1

Individual sample analytical sensitivity $\approx 3 \times 10^6$ f / g PM_{10}

Pooled analytical sensitivity $= {}^{1}/_{\sum(1/sample\ analytical\ sensitivity)}$

Calculating Soil Concentrations

$$\text{Mean} = pooled(AS) \times \sum_{i=1}^{n} f_i$$

$$\text{95UCL} = pooled(AS) \times \left(\sum_{i=1}^{n} f_i\right)_{UCL}$$

where the UCL is based on a chi-square distribution

Examples: Property 1

mean PCMe = $0.071 \times 22 = 1.56 \times 10^6$ f / g PM_{10}

95UCL chrysotile = $0.071 \times 34.9 = 2.48 \times 10^6$ f / g PM_{10}

Asbestos Soil Concentrations
(10^6 fibers/g PM_{10})

Property	Pooled AS (10^6 f/ g PM_{10})	PCMe (mean)	Amphibole (mean/95UCL)	Chrysotile (mean/95UCL)
1	0.071	1.56	0.0 / 0.21	1.77 / 2.48
2	0.070	6.30	0.070 / 0.33	2.03 / 2.78
3	0.373	2.61	0.0 / 1.12	2.24 / 4.42
4	0.373	1.49	0.0 / 1.12	0.0 / 1.12

Adapted from NDEP 2011, Appendix C, Table 2

Calculating Air Concentrations

On-Site Residential Exposure Scenario

PM_{10} conc (g/m^3) = E_{10} (g/m^2-s) $\div$ Q/C_{wind} (g/m^2-s per g/m^3)

E_{10} = wind-related PM_{10} emission flux from soil
Q/C_{wind} = inverse of mean PM_{10} air concentration per unit flux

4.3×10^{-8} g/m^2-s $\div$ 0.043 g/m^2-s per g/m^3 = 1×10^{-6} g/m^3

Examples: Property 1

mean PCMe air conc = 1.56×10^{6} f/g $\times$ 1×10^{-6} g/m^3 = 1.56 f/m^3

95UCL chrysotile air conc = 2.48×10^{6} f/g $\times$ 1×10^{-6} g/m^3 = 2.48 f/m^3

Calculating Cancer Risk

On-Site Residential Exposure Scenario

$$Risk = Conc_{air} \times IUR \times EF \times ED \times (ET_{out} + ET_{in} \times Att) / AT$$

EF = 350 hr/day ED = 30 yr

ET_{out} = 2 hr/day ET_{in} = 16.7 hr/day

Att = indoor air dust attenuation factor = 0.4

Chrysotile IUR for lifetime exposure: 0.057 per f/cm^3

Amphibole IUR for lifetime exposure: 6.3 per f/cm^3

AT = carcinogenic effects averaging time = 70 yr × 365 day/yr × 24 hr/day

Example: Property 1 (combined amphibole and chrysotile risk)

95UCL risk = $[(2.48 \times 10^{-6}\ f/cm^3 \times 0.057\ (f/cm^3)^{-1}) + (0.21 \times 10^{-6}\ f/cm^3 \times 6.3\ (f/cm^3)^{-1})] \times 350 \times 30 \times (2 + 16.7 \times 0.4) / (70 \times 365 \times 24) = 2 \times 10^{-7}$

Comparative Asbestos Residential Risk Estimates

Property	B&C (2003) (mean)	USEPA (mean)	B&C (2003) (95UCL)
1	1×10^{-8}	5×10^{-8}	2×10^{-7}
2	8×10^{-8}	2×10^{-7}	3×10^{-7}
3	2×10^{-8}	9×10^{-8}	1×10^{-6}
4	0	5×10^{-8}	1×10^{-6}

Adapted from NDEP 2011, Appendix C, Table 3

At each location, the mean and 95UCL risk results using the B&C approach bound the risk result using the 2008 EPA Framework approach.

EPA Framework (2008) vs. B & C (2003) Conclusions

- For the southern Nevada properties evaluated, cancer risks estimated by EPA (2008) methods are bounded by B&C (2003) methods
- Even when zero amphibole fibers and 25 chrysotile fibers are counted in 48 samples, the use of a chi-square statistic results in amphibole risk being ~10x higher than chrysotile risk
- B&C results would be higher than EPA (2008) results at sites with predominantly amphibole contamination

Asbestos Sampling, Analysis and Risk Assessment WRAP UP

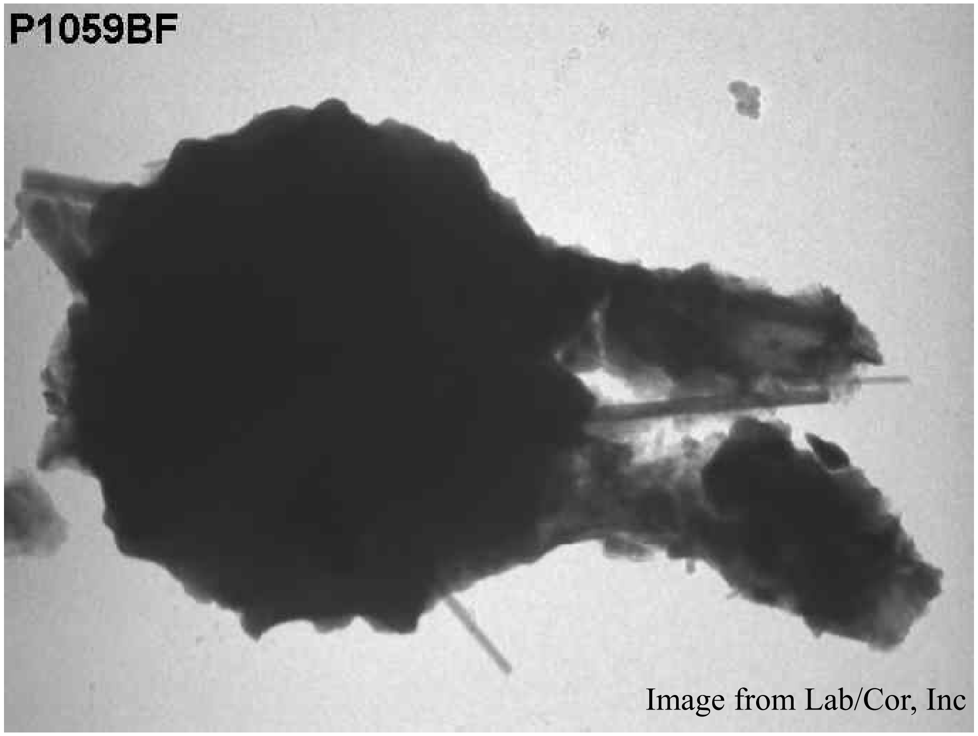


Image from Lab/Cor, Inc

Asbestos Assessment Is Hard

- "Asbestos" isn't easy to define
  - Different mineral types and habits
- "Asbestos" isn't easy to count/quantify
  - Fibers, bundles, clusters, matrices
  - Fiber length, fiber width, aspect ratio

And so, measuring or estimating exposure and determining what components are most harmful is challenging

Asbestos Assessment Is Evolving

Current CERCLA Approach	Changes Afoot
Six types of asbestos defined in 1971	Libby amphibole includes two “new” types of “asbestos, winchite and richterite, which comprise ~95% of asbestos mixture
Fibers defined based on PCM, which underlies EPA’s 1986 IUR	Berman & Crump differentiate cancer potency by fiber type (chrysotile and amphibole) and fiber size based on more recent epidemiology data; method relies on TEM
EPA Framework specifies activity-based sampling	Alternative methods for measuring asbestos in soil and estimating air concentrations may be more representative for a wider range of exposures

Asbestos Assessment Is Evolving

Current CERCLA Approach	Changes Afoot
No estimate of upper confidence limit in exposure concentration (no uncertainty analysis)	Alternative statistical methods to Poisson distribution allow for reasonable estimation of an upper confidence limit with few or no fibers
Only carcinogenic risk evaluated	Draft EPA toxicity assessment for Libby amphibole introduces a reference concentration for noncancer effects